The Future of Human Rights
Impact Assessments of Trade Agreements

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The Future of Human Rights
Impact Assessments of Trade Agreements

De toekomst van mensenrechtelijke effectanalyses van handelsovereenkomsten

(met een samenvatting in het Nederlands)

Proefschrift

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door

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geboren op 12 oktober 1966
te Sydney, Australië

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Prof. mr. W.J.M. van Genugten

In loving memory of my dear cousin Pamela Johnson – who thought of the idea and whose undying patience and generosity in reading and reviewing the text made all the difference.

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Simon Walker

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

ACP	African, Caribbean and Pacific countries
CAFTA	Dominican Republic-United States-Central American Free Trade Agreement
CCSS	Caja Costariccense de Seguridad Social
CEDAW	Convention on the Elimination of All Forms of Discrimination Against Women
CRPD	Convention on the Rights of Persons with Disabilities
EAA	Ecumenical Advocacy Alliance
EC	European Commission
EIAs	Environmental Impact Assessments
EU	European Union
FDI	Foreign Direct Investment
GDP	Gross Domestic Product
HRIAs	Human Rights Impact Assessments
IAIA	International Association of Impact Assessment
ICCPR	International Covenant on Civil and Political Rights
ICERD	International Convention on the Elimination of All Forms of Racial Discrimination
ICESCR	International Covenant on Economic, Social and Cultural Rights
IFC	International Finance Corporation
IIAs	Integrated Impact Assessments of the United Nations Environment Programme
ILO	International Labour Organization
NAFTA	North American Free Trade Agreement
NGO	Non-governmental organization
NHRI	National Human Rights Institution
OECD	Organization for Economic Cooperation and Development
OHCHR	Office of the United Nations High Commissioner for Human Rights
SIAs	Social Impact Assessments
SRSG	Special Representative of the Secretary-General
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
TSIAs	Trade and Sustainability Impact Assessments of the European Commission
UN	United Nations
UNEP	United Nations Environment Programme

UPOV	Union pour la Protection des Obtentions Végétales; Convention for the Protection of New Varieties of Plants.
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

INTRODUCTION

1 THE CALL FOR HUMAN RIGHTS IMPACT ASSESSMENTS OF TRADE AGREEMENTS

It does not take the casual observer too long to identify one or two impacts of trade agreements on life in a globalized world. Public debates on the impact of intellectual property protection on access to HIV treatments caught the public attention earlier this decade as countries struggled to come to terms with the pandemic. Indigenous communities have raised alarms that intellectual property protections were not providing sufficient protection for their cultural heritage and traditional knowledge over plants and seeds, claiming the colonization of such knowledge by outside researchers. The plight of West African cotton farmers or Caribbean banana producers has highlighted concerns that trade agreements might have a negative effect on poverty reduction and development. The debates over the regional trade agreement between Central American countries and the United States (US) and the demonstrations held during trade negotiations in Seattle and elsewhere have highlighted civil society demands for participatory democracy and greater involvement in matters of public interest. Concerns regarding the negative impacts of trade agreements have sparked counter claims that trade agreements promote personal liberty, increase human welfare, make societies more open, strengthen democracy and the rule of law, and promote economic growth and employment.

A robust debate has followed involving environmental, religious and development organizations, trade unions, academics and experts, economists, lawyers, and among them human rights practitioners. Much of the debate has focused on how to retain the advantages of trade openness while avoiding the negative impacts on peoples' lives and habitat. One of the suggestions to flow from the debate has been a call to examine the likely impacts of trade agreements on peoples' lives and on the environment, either prior to the conclusion of the agreement, or at least prior to its implementation, so that protections for people who might lose out from trade openness are built into trade policy-making: impact assessments of trade agreements have been promoted as a means of doing so.[1]

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1 See e.g.: Kirkparick, C., N. Lee and O. Morrissey, 'WTO New Round: Sustainability Impact Assessment Study', Phase One Report, Institute for Development Policy and Management and Environmental Impact Assessment Centre, University of Manchester, 1999; United Nations, *Reference Manual for the Integrated Assessment of Trade-Related Policies*, United Nations Environment Programme, New York and Geneva, 2001.

While economic assessments of trade agreements have existed for decades, these have been insufficient to examine the human dimensions of trade – the impact on people's lives and habitat – successfully. This has led to the development of environmental and social impact assessment methodologies to assess trade agreements in addition, or as an alternative, to economic assessments. In this context, human rights bodies and organizations have joined in the call to move towards evidence-based trade policy-making by proposing human rights impact assessments (HRIAs) of trade agreements.[2] Proponents have suggested that HRIAs would help to provide empirical

2 The UN High Commissioner for Human Rights was one of the first to advocate for such assessments, see e.g.: United Nations, 'Analytical Study of the High Commissioner for Human Rights on the Fundamental Principle of Participation and its Application in the Context of Globalization', Report of the High Commissioner, Commission on Human Rights, (E/CN.4/2005/41: para. 50); United Nations, 'Analytical Study of the High Commissioner for Human Rights on the Fundamental Principle of Non-discrimination in the Context of Globalization', Report of the High Commissioner, Commission on Human Rights, (E/CN.4/2004/40: para. 55); United Nations, 'Human Rights, Trade and Investment', Report of the High Commissioner for Human Rights, Sub-Commission on the Promotion and Protection of Human Rights, (E/CN.4/Sub.2/2003/9: para. 63). States have echoed that call in the context of the Open-Ended Working Group on the Right to Development, see e.g.: United Nations, 'Report of the Working Group on the Right to Development on its Sixth Session', Chairperson-Rapporteur, Ibrahim Salama, Commission on Human Rights, (E/CN.4/2005/25: paras 52-54). Similarly, human rights treaty bodies and Special Rapporteurs have called upon States to undertake assessments of the impact of trade agreements and trade negotiations on the enjoyment of human rights during the consideration of States' periodic reports, see e.g.: United Nations, 'Mission to the World Trade Organization', Report of the Special Rapporteur on the Right to the Highest Attainable Standard of Physical and Mental Health, Commission on Human Rights (E/CN.4/2004/49/Add.1: para. 72); Committee on Economic, Social and Cultural Rights Concluding Observations for Costa Rica (E/C.12/CRI/CO/4: para. 48, January 2008), Morocco (E/C.12/MAR/CO/3: para. 56, September 2006), Ecuador (E/C.12/1/Add.100: para. 55, June 2004); Committee on the Elimination of Discrimination Against Women, Concluding Observations for Colombia (CEDAW/C/COL/C0/6: para. 29, February 2007), Philippines (CEDAW/C/PHI/CO/6: para. 26, October 2006), Guatemala (CEDAW/C/GUA/CO/6: para. 32, June 2006); Committee on the Rights of the Child, Concluding Observations for Ecuador (CRC/C/15/Add.262, paras 20-21, September 2005), and El Salvador (CRC/C/15/Add.232, June 2004). Academics and civil society organizations have also encouraged work on human rights impact assessments of trade agreements, see e.g.: Harrison, J., *The Human Rights Impact of the World Trade Organisation*, Studies in International Trade Law, Vol. 10, Oxford and Portland, Oregon, 2007; Harrison, J., and A. Goller, 'Trade and Human Rights: What does Impact Assessment have to Offer?' *Human Rights Law Review*, 8(4), 2008, 587-615; Lang, A., 'The Role of the Human Rights Movement in Trade Policy-Making: Human Rights as a Trigger for Policy Learning', *New Zealand Journal of Public International Law*, 5, 2007, 147-172; International Federation for Human Rights (FIDH), *Human Rights Impact Assessments of Trade and Investment Agreements concluded by the European Union*, Position Paper, February 2008 (available at: http://www.fidh.org – accessed 17 January 2009); Halifax Initiative, Risk Responsibility and Human Rights: Assessing the Human Rights Impacts of Trade and Project Finance, A discussion paper prepared by the NGO Working Group on EDC: A Working Group of the Halifax Initiative Coalition, Ottawa, 2004, p. 35 (available at: http://www.halifaxinitiative.org/updir/HR_final_report.pdf – accessed 17 January 2009). Recently, the Canadian Parliament has requested a human rights impact assessment of the future free trade agreement with Colombia: House of Commons, Canada, *Human Rights, Environment and Free Trade with Colombia*, Report of the Standing Committee on International Trade, June 2008.

evidence of the real and potential impact of trade agreements on human rights, in turn informing trade policy-making and trade negotiations with evidence-based information, promoting trade agreements that are compatible with the enjoyment of human rights, providing safety mechanisms to avoid human rights violations occurring and remedying abuse if it arises. In the longer term, proponents believe that HRIAs could help to educate human rights practitioners and civil society about trade agreements, and trade practitioners about trade-related human rights issues, stimulating new ways of thinking about trade and trade policies.[3] However, given that environmental and social impact assessment methodologies already exist, the question arises as to whether and how HRIAs bring something new to impact assessment and why an actor should choose to undertake an HRIA in lieu of another form of impact assessment to explore the human dimension of trade agreements. This comes to the central question underlying this thesis – is there value is moving forward with HRIAs in a more systematic manner? However, before proceeding further to express the question formally, it is appropriate to consider in greater detail what HRIAs are, where they have come from and what other impact assessment methodologies could potentially achieve similar ends.

2 THE ORIGINS OF HUMAN RIGHTS IMPACT ASSESSMENTS IN ENVIRONMENTAL AND SOCIAL ASSESSMENT

Human rights impact assessments are a relatively recent phenomenon, owing much to some four decades of environmental and social impact assessment practice. Initially, impact assessment focused on the examination of the likely effects of projects on the environment, particularly aspects such as land-use planning and construction,.[4] Much of the original work began in the 1960s leading, in 1969, to the introduction of the first national impact assessment regime with the adoption of the US National Environmental Policy Act (NEPA).[5] NEPA became the first step in adopting a coherent and systematized process for undertaking environmental impact assessment (EIA) of projects, prompting other countries to develop similar regimes shortly after.[6] However, it soon became clear that the focus on assessment at the project stage had its limits and more effective influence over environmental planning required input at the strategy and policy-making stage prior to project planning.[7] Within this context, the adoption

3 Lang raises the possibility of human rights critiques of trade offering ways to stimulate new ways of thinking about trade policy learning. Lang, *ibid*.

4 Environmental impact assessment came from a mixture of land use planning, modeling and simulation, as well as cost/benefit and multiple objective analysis: Maassarani, T.F., M.T. Drakos and J. Pajkowska, 'Extracting Corporate Responsibility: Towards Human Rights Impact Assessment', *Cornell International Law Journal*, 40, June 2007, 135-169, p. 143.

5 *Ibid*.

6 *Ibid*., p. 144.

7 Gay, R., *Mainstreaming Well-Being: An Impact Assessment for the Right to Health*, University of New South Wales, 2008, p. 8, paper on file with the author.

in 1991 of the *Convention on Environmental Impact Assessment in the Transboundary Context* and the World Bank's Strategic Environment Assessment extended the scope of assessment to cover impact assessment of policies and legislation.[8]

Given the relevance of changes to the environmental on peoples' lives and culture, environmental impact assessment in turn led to the development of methodologies for social impact assessment (SIA). Initial efforts in the 1970s and 1980s focused principally on assessing impacts of development projects on communities, particularly indigenous communities in developed countries.[9] In the 1980's, professionals paid more attention to developing methodological approaches and theory and by the early 1990s, SIAs became a common component of policy-making processes while international organizations such as the United Nations Environment Programme (UNEP) and the World Bank began to integrate SIAs into environmental impact assessments of development projects.[10] In 1994, a group of government officials, academics and practitioners adopted US *Guidelines and Principles for Social Impact Assessment* to assist public and private officials meet the requirements under the NEPA.

These Guidelines, revised in 2003, define social impact assessment 'in terms of efforts to assess, appraise or estimate, in advance, the social consequences that are likely to follow from proposed actions'.[11] Social impacts refer to 'the consequences to human populations of any public or private actions that alter the ways in which people live, work, play, relate to one another, organize to meet their needs and generally cope as members of society. The term also includes cultural impacts involving changes to the norms, values and beliefs that guide and rationalize their cognition of themselves and their society'.[12] In spite of the significant advances in the areas of methodology, theory and practice, SIA has not yet received the same level of official support and acceptance, in particular legal support, as environmental impact assessment, and is still criticized as being descriptive, insufficiently explanatory and atheoretical.[13]

Nonetheless, social impact assessment has advanced considerably and practitioners have recently sought to develop international principles for SIA with the adoption of the International Principles of Social Impact Assessment (the IAIA Principles) in 2003.[14] The International Principles include a set of values to guide the community of SIA practitioners as well as principles to guide SIA practice. Apart from seeking to establish an internationally recognized framework for SIA, the IAIA Principles are also a means of ensuring more systematic and principled practice in response to SIA

8 Maassarani et al, *op.cit.*, p. 144.
9 Barrow, C.J., *Social Impact Assessment: An Introduction*, Arnold, London and New York, 2000, pp. 10ff.
10 Barrow, *ibid.*, p. 13.
11 International Association of Impact Assessment, 'Principles and Guidelines for Social Impact Assessment in the USA: The Interorganizational Committee on Social Impact Assessment', *Impact Assessment and Project Appraisal*, 21(3), 2003, 231-250, p. 231.
12 *Ibid*.
13 Barrow, *ibid.*, p. 14.
14 International Association of Impact Assessment, *Social Impact Assessment: International Principles*, Special Publication Series No. 2, May 2003.

critiques. Today, impact assessment has developed to an extent that there are now a growing number of different types of impact assessment such as health impact assessment, child impact assessment, gender impact assessment, and poverty impact assessment.[15] Human rights impact assessments are among these recent additions to impact assessment literature.

Human rights impact assessments (HRIAs) draw on social scientific analysis and the work in the fields of development studies, monitoring and evaluation, environmental sciences, business administration and public policy, to respond to specific human rights-related needs and concerns.[16] While it is probably fair to say that HRIAs have grown out of SIAs and EIAs, it is also true that human rights principles and standards have influenced existing impact assessment frameworks. For example, the IAIA explicitly incorporates respect for human rights among the core values of social impact assessment.[17]

Human rights impact assessment has developed in response to at least four factors. First, there has been an increasing call, particularly from donor agencies, to assess the extent to which foreign policies and technical cooperation programmes are actually making a difference to human rights enjoyment.[18] This has focused attention on developing impact assessment methodologies that examine the actual impact that programmes – and donor financing – have had in real terms on the enjoyment of human rights. Second, with the increasing interest in rights-based approaches to development among European donor agencies and the United Nations (UN), calls for human rights impact assessments have also arisen with a view to incorporating human rights into development planning and programming, thus encouraging *ex ante* human rights impact assessment prior to decision-making and development programming.

Third, on a parallel track, human rights practitioners, non-governmental organizations, inter-governmental organizations and increasingly business enterprises, have promoted human rights impact assessments as a means of increasing corporate accountability. While some efforts have sought to examine the past effects of business activities, significant attention has focused on incorporating human rights considerations in the decision-making processes of business activities, making up for the lack

15 Hunt, P., and G. MacNaughton, *Impact Assessments, Poverty and Human Rights: A Case Study Using the Right to the Highest Attainable Standard of Health*, Submitted to UNESCO, 2006, p. 10. See also the IAIA website which sets out the abstracts for their 2006 Conference at (http://www.iaia.org/Non_Members/ Conference/IAIA06/abstract%20submissions/view_abstracts.asp – accessed 26 August 2008).

16 Landman, T., *Studying Human Rights*, Routledge, Taylor and Francis Group, London and New York, 2007, pp. 126f, quoting L.B. Mohr, *Impact Analysis for Programme Evaluation*, Sage, Thousand Oaks, California, Second Edition, 1995.

17 The Guiding Principles include: the precautionary principle, the uncertainty principle, intragenerational equity, intergenerational equity, recognition and preservation of diversity, internationalization of costs, the polluter pays principle, the prevention principle, the protection and promotion of health and safety, the principle of multisectoral integration, and the principle of subsidiarity: IAIA (Special Publication Series No. 2), *op.cit.*, pp. 6, 7.

18 Landman, *op.cit.*, p. 126.

of clarity on formal legal responsibilities on business.[19] Fourth, with the increasing focus on cultural, economic and social rights amongst human rights practitioners, greater consideration has been placed on assessing the human rights impact of social and economic policies which may not explicitly intended to affect human rights, but nonetheless do so in unintended ways.

As yet, there is no accepted definition of human rights impact assessments and the development of methodologies has tended to respond to the requirements of assessment as well as past experience. Landman has attempted to categorize HRIAs in four categories, set out below, although the division is somewhat artificial as HRIA methodologies often relate to two or more categories at the same time.[20]

1. *Ex ante* impact assessments of projects, programmes or activities *directly* related to human rights that intentionally seek to ensure that future activities and programmes provoke positive change to the human rights situation.
2. *Ex ante* impact assessments of projects, programmes or activities *indirectly* related to human rights but nonetheless affecting them, such as assessments of the impact of development projects, structural adjustment programmes, investments and the activities of transnational corporations, which do not intend to change the human rights situation but often do unintentionally.
3. *Ex post* impact assessments that examine activities, projects and programmes specifically designed to affect *directly* the enjoyment of human rights with a view to studying how they fared in practice.
4. *Ex post* impact assessments of activities, policies and programmes that have had an *indirect* impact on human rights. As Landman suggests, the impact assessments falling within this fourth category are potentially endless, including examination of the past impact of the practices of multinational enterprises, large scale infrastructure projects, poverty reduction strategies, health policies and so on.

HRIAs of trade agreements assess the impact of trade policies which are not specifically designed with human rights in mind, therefore they fall within the second and fourth categories of human rights impact assessment. In spite of the enthusiasm for HRIAs of trade agreements, relatively little work has focused on developing or testing a methodology. Some conceptual work on methodologies for *ex ante* human rights impact assessments of trade agreements has commenced,[21] and the Thai Human Rights

19 Maassarani et al, *op.cit.*, p. 149. The High Commissioner for Human Rights promoted the development of tools for human rights impact assessment of current and future business activities as a means of helping business enterprises implement their responsibilities: United Nations, 'Report of the High Commissioner for Human Rights on the Responsibilities of Transnational Corporations and Other Business Enterprises with regard to Human Rights', Commission on Human Rights, (E/CN.4/2005/91: para. 52).

20 Landman, *op.cit.*, p. 128.

21 Harrison and Goller, *op.cit*; Walker, S., 'Human Rights Impact Assessments of Trade-related Policies', in M. Gehring and M-C. Segger (eds.), *Sustainable Development in World Trade Law*, Kluwer, The Hague, 2005.

Commission (HRC) has already undertaken an *ex ante* impact assessment of the proposed US-Thai Free Trade Agreement, billed as the first human rights impact assessment of a trade agreement, although the assessment has appeared only in draft form and is methodologically weak.[22] The Costa Rican Defensoría de los Habitantes, the national human rights institution, undertook an *ex ante* impact assessment of the impact of intellectual property provisions of the Dominican Republic-US-Central American Free Trade Agreement in 2005, although without developing an explicit impact assessment methodology or labeling it an impact assessment as such.[23] In addition, the Ecumenical Advocacy Alliance has developed a methodology for *ex post* right to food impact assessment of trade and implemented it through three case studies of rice-farming communities in Ghana, Honduras and Indonesia.[24] In spite of these efforts, there is still not yet a comprehensive methodology for human rights impact assessment of trade agreements.

3 *EX ANTE* IMPACT ASSESSMENTS OF TRADE AGREEMENTS

Human rights impact assessments of trade agreements do not appear in a vacuum but rather appear as the latest attempt at impact assessment of trade agreements, following in the footsteps of economic, environmental and social impact assessment. Indeed, an extensive literature and practice has long existed on *ex ante* and *ex post* assessment of impact of trade agreements.[25] Economic analysis, particularly of the likely input of trade agreements on the economy, production, employment and welfare is common and a detailed science has developed in this field.[26] In the 1990s, the focus on economic impact assessment expanded to include environmental impact assessment, and

22 However, the assessment was never finalized and appears only in draft form, although the draft was made public at a seminar for UN agencies: National Human Rights Commission of Thailand, *Report on Results of the Examination of Human Rights Violations*, Ad-Hoc Coordinating Sub-Committee to Review and Examine the Establishment of the Thailand-United States Free Trade Area, 2006, on file with the author.

23 Defensoría de los Habitantes de la República, ' Consideraciones sobre la salud pública y bioética en materia de propiedad intelectual y medicamentos en el Proyecto de Ley de Tratado de Libre Comercio República Dominicana–Centroamérica–Estados Unidos', (available at: http://www.notlc.com/files/TLC_Anexo_Medicamentos.doc – accessed 2 August 2008).

24 Paasch, A., F. Garbers and T. Hirsch (eds), *Trade Policies and Hunger: The Impact of Trade Liberalization on the Right to Food of Rice Farming Communities in Ghana, Honduras and Indonesia*, Commissioned by the Ecumenical Advocacy Alliance, 2007.

25 For a literature review see: Kirkpatrick, C., N. Lee and O. Morrissey, *WTO New Round Sustainability Impact Assessment Study*, Phase One Report, Institute for Development Policy and Management and Environmental Impact Assessment Centre, University of Manchester, Centre for Research on Economic Development and International Trade, 1999.

26 See e.g., Francois, J.F. and C.R. Shiells, *Modeling Trade Policy: Applied General Assessments of North American Free Trade*, Cambridge University Press, Cambridge, 1994; Piermartini, R., and R. Teh, *Demystifying Modelling Methods for Trade Policy*, WTO Discussion Papers, No. 10, World Trade Organization, Geneva, 2005; Hertel, T., (ed.), *Global Trade Analysis: Modeling and Applications*, Purdue University, Cambridge University Press, 1997.

to a lesser extent social impact assessment, due to a number of factors, including the stronger regulation of the environment in developed countries, the growing interest in the impact of trade on the environment, and the increasing attention paid to trade negotiations surrounding the North American Free Trade Agreement (NAFTA) and the Uruguay Round. In 1994, the Organization of Economic Cooperation and Development (OECD) adapted economic modelling and other assessment techniques to include environmental assessment through its *Methodologies for Environmental and Trade Reviews*.[27] By the late 1990s, practitioners understood the need to examine economic, environmental and social impact together with a view to promoting a comprehensive understanding of trade and its effects. As noted above, today, countries such as, Canada, Norway and the US regularly undertake national environmental reviews of trade policies and several ad hoc initiatives have responded to consider the social and other impacts of recent trade negotiations and agreements.[28]

Practice of *ex ante* impact assessment including a social component has been ongoing for some ten years and there is now a considerable pool of experience in the field. UNEP has undertaken integrated impact assessments (IIAs) over three phases covering eighteen studies in a wide variety of continents, regions, sectors and environmental, social and economic conditions.[29] The European Union has commissioned Trade Sustainability Impact Assessments (TSIAs) of the Doha Round of Multilateral Trade Negotiations as well as of trade agreements and trade relations between the European Union (EU) and the African, Caribbean and Pacific (ACP) countries, Arab States and the Gulf, Mercosur, Chile, countries of the Mediterranean Free Trade Area, Ukraine, China, Korea, India and ASEAN countries.[30] Other ad hoc examples of impact assessment of trade agreements including a social component also exist.[31]

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27 Organization of Economic Cooperation and Development (OECD), *Methodologies for Environmental and Trade Reviews*, OECD, Paris, 1994; Organization of Economic Cooperation and Development, *Assessing the Environmental Effects of Services Trade Liberalization: A Methodology*, Joint Working Party on Trade and Environment, Paris, 2002, (COM/TD/ENV(2000)123/FINAL).

28 European Commission, *Handbook for Trade Sustainability Impact Assessment*, European Commission, External Trade, 2006, p. 10; Harrison and Goller, *op.cit.*

29 United Nations, *Integrated Assessment of the Impact of Trade Liberalization on the Rice Sector*, UNEP Country Projects Round III, A Synthesis Report, United Nations Environmental Programme, Geneva and New York, 2005 (China, Colombia, Côte d'Ivoire, Indonesia, Nigeria, Senegal, Vietnam); United Nations, *Integrated Assessment of Trade Liberalization and Trade-Related Policies*, UNEP Country Studies – Round II, A Synthesis Report, United Nations Environmental Programme, Geneva and New York, 2002 (Argentina, China, Ecuador, Nigeria, Senegal, Tanzania); United Nations, *Trade Liberalization and the Environment: Lessons Learned from Bangladesh, China, Philippines, Romania and Uganda*, A Synthesis Report, United Nations Environmental Programme, Geneva and New York, 1999.

30 See the European Commission's official website on Trade Sustainability Impact Assessments (available at: http://ec.europa.eu/trade/issues/global/sia/studies.htm – accessed 12 September 2008).

31 For a full list, see the table at: http://www.nottingham.ac.uk/law/hrlc/business-trade/Human_Rights_Impact_Assessments.php (accessed 12 September 2008).

While these efforts have been widely welcomed, they have also provoked several criticisms.[32] In particular, the social analyses of the IIA and TSIA frameworks have tended to be diluted by the fact that the assessments have examined economic and environmental impacts as well as social impacts. The weight of considering impacts over three sectors has affected the depth of social analysis at the risk of leaving potential social impacts undiscovered, or alternatively, justifying certain negative social impacts in light of the existence of likely positive economic or environmental impacts. Further, some ad hoc attempts at social impact assessment of trade agreements have tended to suffer from weak methodologies. Some criticisms have focused specifically on the European Union's TSIA studies and have highlighted the lack of sufficient consultation and participation of stakeholders in the process of impact assessment, the pro-liberalization and pro-economic basis of the analysis, the lack of justification for the choice of sustainability indicators, the weak mitigation and enhancement measures proposed as well as the failure of TSIAs to influence trade negotiations. In spite of these criticisms, the knowledge and experience of *ex ante* impact assessments of trade agreements provides valuable insights to assist with the development of an HRIA methodology.

4. RESEARCH QUESTION AND STRUCTURE

A question that arises from the brief introduction to HRIAs of trade agreements in the previous paragraphs is whether HRIAs add anything new to the range of impact assessment methodologies that already exist as a means of evaluating the impact of trade agreements and why someone seeking to explore the human dimensions of trade agreements would choose to undertake an HRIA in lieu of a sustainable, integrated, social or other impact assessment. At the heart of this critical question is whether there is a difference between a 'human rights' impact assessment methodology and a 'social' impact assessment methodology and whether that difference, if any, is sufficient to convince actors to undertake human rights impact assessment of a trade agreement in a comprehensive manner. For example, is a 'right to health' assessment of a trade agreement any different to a 'health' assessment of a trade agreement and if so, what are the advantages and disadvantages of choosing a 'right to health' impact assessment

32 FIDH, *op.cit.*; Harrison and Goller, *op.cit.*; Blobel, D., M. Knigge and B. Görlach, *Report on Trade, Environment and Sustainability Impact Assessment*, Concerted Action on Trade and Environment, 2005; 'EU Trade and Sustainability Impact Assessments: A Critical View', Statement of European Civil Society Organizations, 2006 (available at: http://www.foeeurope.org/publications/2006/ siastatement_eucivilsociety_oct2006.pdf – accessed 17 January 2008); Richardson, S., *A 'Critique' of the EC's WTO Sustainability Impact Assessment Study and Recommendations for Phase III*, Paper commissioned by Oxfam GB, WWF European Policy Office, Save the Children, ActionAid, London, 2000; SUSTRA, 'Sustainability Impact Assessment', Policy Brief Paper, Trade Societies and Sustainable Development SUSTRA Network, based on the conclusions of the SUSTRA seminar on 'Sustainability Impact Assessment', Centre for Philosophy of Law, Université catholique de Louvain, Louvain-la-Neuve, Belgium, 26-27 March 2003.

methodology? The question is important as it clarifies the case for HRIAs of trade agreements and provides the basis of encouraging States and other actors to undertake human rights impact assessments on a regular basis as part of the process of developing trade policy and negotiating new trade agreements.

This leads to the central question of the present dissertation which is the following:

Is there value in undertaking HRIAs of trade agreements in a more systematic manner?

In order to answer this question, answers to two initial questions are necessary:

1. *What benefits do HRIAs offer to the assessment of trade agreements?*
2. *What are the risks involved in undertaking HRIAs?*

In balancing the benefits and risks associated with them, it is possible to identify whether it is worth moving forward to test HRIAs of trade agreements further and encourage governments and other actors to undertake them on a more systematic basis. 'More systematic' means for present purposes moving forward to a systematic testing of the methodology developed in this thesis through, for example, a series of country studies.

The terrain is vast and so I have narrowed the focus in two specific areas: first, by focusing on *ex ante* impact assessment – forward looking assessments undertaken prior to, during or shortly after trade negotiations with a view to predicting outcomes; and, second, by focusing on assessment at the country level. I justify the specific focus on *ex ante* impact assessments, as opposed to *ex post* assessment, on the basis that *ex ante* impact assessment has greater potential to provide an immediate impact on the content and implementation of emerging trade rules and policies. The focus on the country level, as opposed to assessing the global or regional impact of trade agreements, permits close analysis of the impact of trade agreements on the lives of individuals, a factor which is ultimately the driving force behind any human rights analysis. I undertake a combination of both theoretical analysis as well as a case study: the theoretical analysis provides the basis for the development of the methodology, while the case study provides insights into how theory plays out in practice – an important factor to bear in mind with impact assessments which are ultimately practical in nature.

I develop and illustrate a methodology for human rights impact assessments of trade agreements in four chapters. In Chapter I, I develop a human rights framework for impact assessment. I define human rights by reference to international human rights law and identify who are the beneficiaries of human rights and who have responsibilities towards human rights for the purposes of developing a methodology for human rights impact assessments of trade agreements. I then adapt existing frameworks relating to a 'rights-based approach to development' to identify the four basic elements that comprise a human rights framework for impact assessment, namely: first, human rights should be the explicit subject of a human rights impact

assessment; second, the process of the impact assessment should respect human rights; third, the impact assessment should contribute to developing the capacities of States and other actors who have duties to protect and promote human rights, as well as of individuals and groups who are the beneficiaries of human rights; and, fourth, the impact assessment should involve human rights mechanisms and actors, such as treaty bodies and national human rights institutions. I then identify the areas of overlap between the human rights framework and two frameworks for social impact assessment and conclude that the human rights framework does indeed have original aspects. This statement is important as it helps to identify later in the thesis the potential benefits of using HRIAs as a means of analyzing the future impacts of trade agreements.

In Chapter II, I apply this framework to develop a methodology for human rights impact assessments of trade agreements. To do so, I rely on the considerable amount of academic, civil society and inter-governmental work that has evolved over the last ten years of debate over the impact of trade agreements on human rights. I also adapt existing materials on integrated and sustainable impact assessment of trade agreements, as well as materials on human rights impact assessments of projects and policies unrelated to trade agreements to develop the methodology in light of the human rights framework developed in Chapter I. I explain how the various trade measures comprising trade agreements relate to human rights and, relying on secondary materials, identify those trade sectors which should be the primary focus of impact assessments. On the basis of the considerable academic, non-governmental organizations' (NGO) and inter-governmental material relating to the 'human rights and trade' debate, I provide a 'categorization' of ten impacts to assist in the analysis of human rights impacts of trade agreements. I provide a step-by-step process for undertaking human rights impact assessments of trade agreements and finally I turn to data collection and analysis, identifying criteria to assist in choosing human rights indicators as well as the various techniques for collecting and analyzing data.

Chapter III then illustrates the methodology through a case study. The case study examines the impact of the Dominican Republic-Central American-US Free Trade Agreement (CAFTA) on human rights, with a specific focus on the impact of CAFTA's intellectual property provisions on access to medicines and human rights. The case study is only an illustration of the methodology and does not constitute either a complete implementation of the methodology or a testing of the methodology. For example, a complete implementation of the methodology would focus not only on access to medicines but also on other aspects of CAFTA, such as its impact on rural livelihoods or on universal access to essential services. Similarly, a full testing of the methodology would normally involve undertaking at least two and preferably more case studies and comparing the results. In order to do this, a broader range of talents would be necessary, comprising not only a lawyer but also at least an economist and a social scientist. The objectives of undertaking the case study are therefore more modest: to illustrate how the methodology looks in practice; and to provide some

insights into whether human rights impact assessments of trade agreements have any 'added value'.

The fourth and final Chapter examines the methodology critically to weigh the benefits and risks of HRIAs of trade agreements and conclude whether there is a sufficient argument to proceed to test the methodology comprehensively and to encourage States and others to undertake such assessments in a sustained way. In order to answer the question, I take the original aspects of the human rights framework identified in Chapter I and examine the benefits they offer to impact assessment of trade agreements, using examples from the Costa Rican case study where appropriate. I also examine the risks involved in undertaking human rights impact assessments, particularly risks of a political nature but also in terms of the time and resource challenges facing human rights impact assessments.

I then make some observations on the methodology and whether it warrants moving forward to comprehensive testing and sustained implementation of human rights impact assessments of trade agreements. I observe that there is indeed value in undertaking HRIAs of trade agreements, in particular by providing a legal framework by which to analyze and interpret impacts and by providing a means of holding States and possibly others accountable. These are factors which are inherent to human rights impact assessments and which other frameworks, such as social impact assessments, do not share to the same extent. However, the weaknesses and risks implicit in the human rights framework also indicate that human rights impact assessments might not always add value and might even have the opposite effect, in particular in relation to governments that are particularly sensitive to their human rights record. Consequently, there is no clear result of whether the benefits of HRIAs outweigh the risks; however, in conclusion, I set out a list of three criteria to indicate the situations in which human rights impact assessments are more likely to have an added value, offering something above and beyond other impact assessment frameworks. The next step, beyond the scope of this thesis, will be to test the methodology identified here and promote States and other actors to undertake HRIAs as part of the process of negotiating new trade agreements.

CHAPTER I
A HUMAN RIGHTS FRAMEWORK FOR IMPACT ASSESSMENT OF TRADE AGREEMENTS

1 INTRODUCTION

The term 'human rights' can mean different things to different people. In discussions on trade, some commentators have focused on the protection of labour standards, others have focused on the use of trade bans to punish States for grave and systematic violations of human rights, others have focused on the right to health and access to medicines, while others have claimed that the rules of the World Trade Organization (WTO) have a constitutional function akin to acknowledging a human right to freedom of trade. Chapter I clarifies what is meant by the term 'human rights' in the present thesis. The thesis adopts a legal positivist approach which perceives human rights as those civil, cultural, economic, political and social rights recognized in international law. The Chapter justifies this definition and explains the various consequences relevant to conducting human rights impact assessments of trade agreements. Having clarified the meaning of the term 'human rights', the Chapter proceeds to develop a human rights framework for impact assessment to inform the HRIA methodology of trade agreements developed in Chapter II and illustrated in Chapter III.

2 HUMAN RIGHTS: WHAT RIGHTS, WHOSE RIGHTS AND WHOSE OBLIGATIONS?

2.1 What human rights are subject of impact assessments of trade agreements?

Given the widely diverging opinions on the content and status of human rights expressed by philosophers, lawyers, academics, religious leaders, politicians and others, it is important to clarify at the outset what the term refers to for purposes of developing a methodology for human rights impact assessments of trade agreements. This thesis refers to human rights as those civil, cultural, economic, political and social rights recognized in international human rights instruments, many of which are also recognized as part of customary international law.[1] International human rights

1 In addition to the Universal Declaration of Human Rights and the Declaration on the Right to Development, the nine core human rights treaties are: the International Covenant on Economic, Social and Cultural Rights, the International Covenant on Civil and Political Rights, the International Convention on the Elimination of All Forms of Racial Discrimination, the International Convention on the Elimination of All Forms of Discrimination against Women, the Convention against Torture and other Cruel, Inhuman or Degrading Treatment or Punishment, the Convention on the Rights of the Child, the International Convention on the Rights of Migrant Workers and Members of Their Families, and the Convention on the Rights of Persons with Disabilities. As of April 2009, the International Convention

instruments and customary international law provide a reliable, objective and globally valid source of human rights. The nine core UN human rights treaties expressly refer to the universality of human rights and all States have ratified at least one of these instruments – indicating a level of global acceptance of human rights – and have reiterated their commitment to human rights through political declarations and resolutions of the UN General Assembly.[2] While the universality of human rights is sometimes contested through arguments of cultural relativism,[3] international human rights law remains the most authoritative and globally relevant source of human rights, making it particularly relevant to discussions revolving around international trade and globalization. This approach adds legitimacy to the analysis, while avoiding the diverging philosophical approaches to human rights beyond international law.

Of course, trade agreements might not necessarily affect all civil, cultural, economic, political and social rights. Indeed, much of the following discussion focuses on cultural, economic and social rights. However, the understanding in the present thesis is that, when using the term 'human rights', the term refers to rights recognized in international law but not other so-called 'rights' that some commentators promote, such as a right to freedom of trade – a parallel discussion which is touched on below.

The primary sources of human rights are therefore the UN human rights instruments as well as customary international law. Where additional clarity is necessary on the scope and meaning of particular provisions in human rights treaties, the authoritative work of the UN expert treaty bodies is relied upon, in particular the General Comments of treaty bodies, as well as the work of the special procedures of the UN Human Rights Council.[4] The General Comments provide authoritative statements concerning

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on Enforced and Involuntary Disappearances has not yet entered into force. In addition, 182 Conventions of the International Labour Organization as well as the four Conventions and two Protocols codifying international humanitarian law also provide sources of human rights law. The content of customary international human rights law is disputed. Recently, Clapham has suggested the following list of human rights norms potentially forming part of customary international law: the rules prohibiting arbitrary killing, slavery, torture, detention and systematic racial discrimination, the right to self-determination, the right to basic sustenance, freedom of opinion, equality rights, the right to a fair trial, the right to free choice of employment, the right to form and join trade unions, and the right to free and compulsory primary education, although he notes that the permissible restrictions applying to many of these rights require a more detailed examination in order to determine the parameters of customary obligation. Clapham, A., *Human Rights Obligations of Non-State Actors*, Oxford University Press, Oxford, 2006, p. 86. Clapham's listing compares with older authoritative listings, such as the *Restatement (Third) Foreign Relations Law of the United States* which failed to include any references to economic, social and cultural rights: American Law Institute's *Restatement (Third) Foreign Relations Law of the United States* (1987), Vol. 2, 161, para. 702.

2 See e.g.: Vienna Declaration and Programme of Action, World Conference of Human Rights (1993); United Nations Millennium Declaration, General Assembly resolution 55/2 (2000).

3 For a discussion of cultural relativism and the universality of human rights, see: Donnelly, J., *Universal Human Rights in Theory and Practice*, Second Edition, Cornell University Press, 2005, pp. 89ff.

4 With the exception of the International Covenant on Economic, Social and Cultural Rights (ICESCR), the core human rights treaties establish treaty bodies – committees of experts acting in their independent capacity that are tasked with various functions, including the review of reports submitted

the application of specific articles of human rights treaties. While the General Comments do not provide definitive interpretations of the treaties, States and other actors have widely recognized their relevance to explaining practical issues relevant to implementation of the treaties and it is on this basis that they are referred to. The work of the special procedures of the Human Rights Council provides useful and authoritative insights into the application of human rights treaties in specific situations or countries. Other sources of human rights referred to are the human rights treaties of the Council of Europe, Organization of American States and the African Union.[5] As this thesis seeks to provide a globally relevant methodology, it refers to regional instruments as secondary sources. However, it is important to note that the national implementation of the methodology might require its adaptation to take into account the particular exigencies of regional and national human rights law.

The comprehensive nature of human rights, covering civil, cultural, economic, political and social rights, highlights the fact that human rights law perceives human dignity in broad terms. This has important implications for using human rights law as a framework for impact assessment. Two factors are important to emphasize. First, it means that an HRIA must look beyond economic growth, wealth creation and employment as a measure of the effectiveness of trade agreements and consider impact on several levels – political, social, cultural as well as economic. Second, an HRIA has to examine how impacts on one right might affect impacts on other rights. Lack of employment can block access to education, but education can provide the means to a better income.

Finally, the present thesis refers to civil, cultural, economic, political and social rights as having essentially the same nature. While such a position is in keeping with the scheme of the Universal Declaration and later human rights treaties such as the Convention of the Rights of the Child and the Convention on the Rights of Persons with Disabilities which recognize all rights on an equal level, several reasons, principally Cold War tensions, led to a categorization of rights into civil and political rights and economic, social and cultural rights which sometimes persists even today.[6] This view perceives civil and political rights as essentially freedoms from State abuse, and

periodically by States parties setting out the steps undertaken to implement the convention. In relation to ICESCR, the UN Economic and Social Council established a body which, for all intents and purposes, has the same authority and functions as other treaty bodies.

5 See e.g.: in the Council of Europe, the European Convention for the Protection of Human Rights and Fundamental Freedoms (1950) and the European Social Charter (1961) and its revisions; in the Organization of American States (OAS), the American Convention on Human Rights (1969) and the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights; in the African Union, the African Charter on Human and Peoples' Rights (1981).

6 Scott identifies three reasons for the separation of rights into two Covenants: ideological (including the belief that economic, social and cultural rights were not justiciable and required different means of implementation); political; and practical. See Scott, C., 'The Interdependence and Permeability of Human Rights Norms: Towards a Partial Fusion of the International Covenants on Human Rights', *Osgoode Hall Law Journal*, 27(4), (1989), 770-878, pp.794f.

economic, social and cultural rights as entitlements or even programmatic goals but not freedoms in the sense of civil and political rights. It is now widely recognized that all rights have elements of both freedom from State intervention as well as entitlements to State intervention in certain situations, underlying the essentially similar nature of all rights.[7] Moreover, doubts over the legal nature of economic, social and cultural rights have been widely dispelled in light of the increasing national and regional jurisprudence on economic, social and cultural rights[8] as well as the recent adoption of an Optional Protocol to the International Covenant on Economic, Social and Cultural Rights which will permit individuals to petition the relevant Committee with complaints of alleged violations.[9] Given the potential of trade agreements to affect a wide range of rights – from political rights to workers' rights to the principle of non-discrimination and to cultural rights – it is important to clarify at the outset that the methodology treats these rights as of essentially the same nature. This is not to say that all rights are exactly the same or require the same measures of protection or implementation. However, differences between rights are differences of degree only and are not categorical.

7 Donnelly, J., *Universal Human Rights in Theory and Practice*, Cornell University Press, United States of America, 2005, p. 30. See also the General Comments of the Committee on Economic, Social and Cultural Rights such as the General Comment on the Right to Health which state that rights consist of both freedoms and entitlements: e.g.: United Nations, 'The Right to the Highest Attainable Standard of Health', Committee on Economic, Social and Cultural Rights, General Comment No. 14, (E/C.12/2000/4).

8 At the national level, judicial decisions on complex social and economic issues in South Africa, India, Portugal, Finland, Latvia, Argentina, Colombia, Brazil, the United States and other countries have demonstrated that courts can and are adjudicating economic, social and cultural rights. See e.g., *Nilson E. Pinilla Pinilla* (No. de Radicación 4501), Supreme Court of Justice, Bogota, Colombia; *People's Union for Civil Liberties v Union of India & Ors*, Writ Petition [Civil] No. 196 of 2001, Supreme Court of India; *Campaign for Fiscal Equity et al v. The State of New York et al*, 719 N.Y.S. 2d 475 (2001); Supreme Court of New York; *Chameli Singh & Ors.v State of U.P & Anor* (1996) 2 SCC 549, Supreme Court of India; *The Government of South Africa v Grootboom & Ors*, 2001 (1) SA 46 (CC); *Soobramoney v. Minister of Health* Constitutional Court of South Africa, 1998 (1) SA 765 (CC), 1997 (12) BCLR 1696; *Minister of Health and Others v. Treatment Action Campaign* South African Court of Appeal 2002 (5) SA 721, 2002 10 BCLR 1033; Case No. 590/2004 of the Portuguese Constitutional Court (Tribunal Constitucional, Processo No. 944/03). See also: Gauri, V., and D.M. Brinks (eds), *Courting Social Justice: Judicial Enforcement of Social and Economic Rights in the Developing World*, Cambridge University Press, Cambridge, 2008.

9 The adoption of the Optional Protocol to the International Covenant on Economic, Social and Cultural Rights on 10 December 2008, the 60th anniversary of the Universal Declaration, was hailed not only as a means of giving individuals an avenue of petition to the Committee on Economic, Social and Cultural Rights in the case of alleged violations of the Covenant but also as a confirmation of the indivisibility and interdependence of all rights: 'Closing a historic gap in human rights', United Nations Press Release available at:http://www.unhchr.ch/huricane/huricane.nsf/0/D39BD9ED5406650 FC125751C0039FE08?opendocument (accessed 15 August 2009).

2.2 Are market freedoms human rights?

Of particular relevance to clarifying the term 'human rights' in the context of developing a methodology for HRIAs of trade agreements, is the need to understand the relationship between human rights and market freedoms. Some commentators have equated trade rules promoting market freedoms with human rights, in ways that would effectively acknowledge a human right to freedom of trade.[10] Characteristic of this position is the work of Ernst-Ulrich Petersman who promotes a constitutional function for WTO law, according to which WTO 'guarantees of freedom' would be directly applicable in favour of individual citizens in much the same way that an individual claims human rights through domestic courts[11] – effectively amounting to a call for the recognition of a human right to free trade. Charnovitz sums up this approach as follows: '[b]ecause it enhances both due process and property rights of economic actors, the WTO is more than a commercial agreement, it is also a human rights agreement'.[12]

It is relevant to observe that some human rights are certainly crucial 'freedoms' that are important for well-functioning markets. For example, Article 6 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) includes the right of everyone to the opportunity to gain his living by work which he freely chooses or accepts. To a limited extent, international human rights law also acknowledges a right to own property alone as well as in association with others.[13] Importantly, both Covenants include 'property' as one of the prohibited bases of discrimination. Other human rights are relevant to the participation of the individual in markets such as the right to freedom of movement, the right to freedom of expression and the protection of the rights of migrant workers. To the extent that the protection of human rights is

10 The most significant proponent of constitutional functions for the WTO is Ernst-Ulrich Petersmann. See e.g., Petersmann, E., 'Human Rights and International Economic Law in the 21st Century: The Need to Clarify their Interrelationships', *Journal of International Economic Law*, Volume 4(1), 2001, 3-39; Petersmann, E., 'Human Rights and International Trade Law: Defining and Connecting the Two Fields' in T. Cottier, J. Pauwelyn and E. Bürgi (eds), *Human Rights and International Trade*, Oxford University Press, Oxford, 2005, pp. 20-95. See also: Anderson, R.D., and H. Wager, 'Human Rights, Development, and the WTO: The Cases of Intellectual Property and Competition Policy', *Journal of International Economic Law*, 9(3), (2006), 707-747. Other writers, such as Amartya Sen, have recognized that the denial of opportunities of transaction in the market place could itself be a source of unfreedom, although he appears to accept that a freedom to undertake transactions and exchange might not be inviolable or a fundamental human right as such: Sen, A., *Development as Freedom*, Oxford University Press, Oxford, 1999, pp. 25f.

11 Petersmann, E., 'Human Rights and International Economic Law in the 21st Century: The Need to Clarify Their Interrelationships', *op.cit.*, p. 33f.

12 Charnovitz, S., 'The WTO and the Rights of the Individual', *Intereconomics*, March/April 2001, p. 28.

13 Recognized in Article 17 of the UDHR, although not in the two Covenants. Nonetheless, ICERD (Article 5) prohibits discrimination in relation to the right to own property and CEDAW (Articles 15 and 16) recognizes equal rights for men and women to conclude contracts and administer as well as dispose of property.

necessary for the effective functioning of markets, existing UN human rights standards might already be sufficient. However, the sum of these elements does not amount to a free-standing human right to freedom of trade which would also include freedom of contract, freedom to move goods and services across borders and the protection of property rights such as intellectual property rights not typically recognized as inviolable human rights.

Unsurprisingly, the proposal to recognize constitutional functions for WTO law has been controversial.[14] Much of that criticism has focused on Petersmann's methodology, his theories of constitutionalism as well as his characterization of human rights and their role in the WTO. In addition, Petersmann's arguments raise three important concerns which should be flagged. First, the link between free trade and individual human dignity would appear to be tenuous given that the direct beneficiaries from free trade are generally not individuals but rather business enterprises. This is not to say that individuals do not benefit, for example, as consumers, and some individuals, such as migrant workers, do of course engage directly in trade. However, in today's era of globalization, the principal traders tend to be corporations rather than humans, thus making the link to human dignity unclear. Second, the various freedoms and rights under trade law that Petersmann refers to are more easily characterized as instrumental rights relevant to promoting human rights, rather than stand-alone human rights. For example, intellectual property rights are instrumental rights to the extent that they protect the moral and material interests of individual authors and inventors. However, intellectual property rights are not inviolable, they can be licenced or waived, and can be constrained, for example, to protect access to essential medicines for all.[15] The same

14 See e.g., Alston, P., 'Resisting the Merger and Acquisition of Human Rights by Trade Law: A Reply to Petersmann', Public Law and Legal Theory Working Paper Series, Research Paper No. 46, New York University Law School, August 2002; Howse, R., and K. Nicolaidis, 'Legitimacy and Global Governance: Why Constitutionalizing the WTO is a Step Too Far' in T. Cottier and P.C. Mavroidis (eds), *The Role of the Judge in International Trade Regulation: Experienceand Lessons for the WTO*, World Trade Forum, Vol. 4, University of Michigan Press, Ann Arbor, Michigan, 2003, 307-48; Howse, R., *Human Rights in the WTO: Whose Rights, What Humanity?: Comment on Petersmann*, Contribution to Jean Monnet Working Paper No. 12/02, Symposium: Trade and Human Rights: An Exchange, New York School of Law, New York, 2002; Peers, S., 'Fundamental Rights or Political Whim? WTO Law and the European Court of Justice' in G. de Burca and J. Scott (eds), *The EU and the WTO*, Hart Publishing, U.K. 2001, p. 111.

15 The Committee on Economic, Social and Cultural Rights has clearly distinguished intellectual property rights from the right of authors to the moral and material benefits in their works recognized under Article 15(1)(c) of the Covenant. Intellectual property rights might be instrumental in meeting the requirements of Article 15(1)(c) through promoting innovation and rewarding individual authors and inventors. However, the temporary nature of intellectual property rights (they can be revoked, licenced and assigned to someone else) underline their instrumental rather than fundamental nature. The Committee has distinguished this instrumental role from the fundamental purpose of Article 15(1)(c) to protect the inherent dignity of individual authors. United Nations, 'The Right of Everyone to Benefit from the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of which He or She is Author', Committee on Economic, Social and Cultural Rights, General Comment No. 17, (E/C.12/GC/17: paras 1-3).

could be said for freedom of contract. Third, while trade has important welfare increasing benefits for human beings, including those living in poverty, trade freedoms may also pose challenges to the enjoyment of human rights. Elevating free trade to the status of a human right – in other words linking free trade to the fundamental elements necessary to live a dignified life – might place trade measures beyond criticism and make trade liberalism an end in itself rather than a means to an end. For these reasons, the methodology does not consider 'market freedoms' to be human rights for the purpose of impact assessment of trade agreements.

2.3 Whose rights are subject of Human Rights Impact Assessments of trade agreements?

Having clarified what is meant by the term 'human rights', it is relevant to identify which individuals or groups are 'rights-holders' and therefore the subjects or beneficiaries of HRIAs of trade agreements. Under UN human rights law, individuals, with very few exceptions, are the beneficiaries of human rights. This position is drawn from the Universal Declaration of Human Rights which stipulates that '[a]ll human beings are born free and equal in dignity and rights'.[16] As Donnelly has observed, '[i]f human rights are the rights that one has simply as a human being, then only human beings have human rights; if one is not a human being, by definition one cannot have human rights'.[17] Human beings are essentially individuals although there are some notable exceptions. The right to self determination in both Covenants is a right of 'peoples' as a collective group of individuals. Similarly, trade unions have certain rights under the International Covenant on Economic, Social and Cultural Rights.[18] The International Covenant on Civil and Political Rights recognizes rights of individuals in minorities to their culture.[19] There are several consequences flowing from this which are important to consider in developing a methodology for HRIAs of trade agreements.

First, corporations, by virtue of not being human beings, are not 'rights-holders', at least under UN human rights law. The UN Declaration on Human Rights recognizes that '(a)ll *human beings* are born free and equal in rights' in Article 1, while Article 2 recognizes that '*(e)veryone* is entitled to the rights and freedoms set forth in this Declaration' (emphasis added). Thus, under UN human rights law, a pharmaceutical company could not make a claim that its fundamental and inalienable right to intellectual property protection – the right of authors to the moral and material interests in works as recognized in Article 15 of the International Covenant on Economic, Social

16 UDHR, Article 1.

17 Donnelly, J., *Universal Human Rights in Theory and Practice*, Cornell University Press, New York, 2005, p. 25.

18 International Covenant on Economic, Social and Cultural Rights, Article 8 recognizes the right of trade unions to establish national federations and the right of national federations to form or join international trade-union organizations, as well as the right of trade unions to function freely.

19 ICCPR, Article 27.

and Cultural Rights – might be infringed by the grant of a compulsory licence.[20] The methodology maintains the position in UN instruments given the global reach of these instruments. However, future implementation of the methodology in country specific assessments might require reconsideration of the issue, particularly given that regional human rights law is not always consistent with UN law. Within the Council of Europe, the European Convention on Human Rights allows non-governmental organizations claiming to be the victim of a violation of any of the Convention rights to bring a claim before the European Court of Human Rights.[21] This clearly provides an avenue for corporate bodies to bring claims of human rights violations and has enabled corporations to bring a series of trade-related cases before the European Court in areas such as protection of the right to property, including intellectual property, freedom of expression and protection of a fair and public hearing within a reasonable time by an independent and impartial tribunal.[22]

Second, HRIAs of trade agreements should consider impact on the rights of non-nationals, given that international trade involves not only the transborder movement of goods and services, but also of traders and service providers. This is particularly so in the field of service provision where individuals cross borders to supply or use services. Examples include health professionals moving temporarily overseas to work or patients or students travelling for treatments or studies. At times, these suppliers or beneficiaries of trade might be in a vulnerable position, for example, through inadequate protection of labour rights or medical coverage in the case of emergency illness. Most human rights treaties identify obligations on States that cover both nationals and non-nationals. In relation to civil and political rights, the Human Rights Committee has noted that 'the rights set forth in the International Covenant on Civil and Political Rights apply to everyone, irrespective of reciprocity, and irrespective of his or her nationality or statelessness … [T]he general rule is that each one of the Covenant rights must be guaranteed without discrimination between citizens and aliens'.[23] The basic position under ICESCR is that States must guarantee economic, social and cultural rights to non-citizens; however, developing countries, with due regard for

20 See e.g. discussions in: Walker, S., 'A Human Rights Approach to the WTO's TRIPS Agreement', in Abbott, F.M., C. Breining-Kaufmann and T. Cottier (eds), *International Trade and Human Rights: Foundations and Conceptual Issues*, Studies in International Economics, The World Trade Forum, Vol. 5, University of Michigan Press, Ann Arbor, Michigan, 2006, 171-180, p. 177. The Committee on Economic, Social and Cultural Rights indicated its view on the matter in General Comment No. 17 by stipulating the difference between the human right of authors to the moral and material interests in their works and intellectual property protection. While the former seeks the protection of the personal connection between an author and a work, the latter protects principally corporate interests. CESCR, General Comment No. 17, *op.cit.*, para. 2.

21 European Convention on Human Rights, Article 63(4).

22 See Kälin, W., 'Trade and the European Convention on Human Rights', in Abbott, Breining-Kaufmann and Cottier, *op.cit.*, pp. 290-295.

23 United Nations, 'The Position of Aliens under the Covenant', Human Rights Committee, General Comment No. 15, (1986), paras 1-2.

human rights and their national economy, may determine to what extent they guarantee economic rights to non-citizens.[24]

Third, considering individuals as the beneficiaries of human rights highlights the fact that HRIAs of trade agreements have to measure impact in terms of individual rather than aggregate welfare. Accordingly, if average incomes for the population increase, but the incomes of the poorest segments of the population decrease, the result could exacerbate existing inequalities and discrimination in society amounting to an abuse of human rights. This is particularly so where women, racial minorities, indigenous peoples, persons with disabilities and so on are disproportionately represented in those populations. Combatting discrimination is not simply a matter of prohibiting acts of discrimination or discriminatory legislation, but also entails an obligation on the State to take action to reverse the underlying biases in society that have led to discrimination and, where appropriate, take temporary special measures in favour of people living in disadvantaged situations so as to promote substantive equality.[25]

2.4 What actors are subject to human rights impact assessments of trade agreements?

States are the primary duty-bearers of human rights under international law and ratifying States of international instruments accept legally binding obligations in relation to the provisions of those treaties. However, other actors, such as corporations, the international community and even civil society organizations such as non-governmental organizations, trade unions and corporate lobby groups, as well as individuals, also have some sort of moral duty towards respecting human rights.[26] This section considers the duties on States, corporations and the international community – the more relevant actors in the field of the negotiation and implementation of trade agreements.

24 ICESCR, Article 2(3). The obligations under ICESCR should also be read with ILO treaties which protect the rights of workers generally such as equality of treatment, equal remuneration and minimum wage irrespective of citizenship although some rights such as equal opportunity and vocational training are extended only to those lawfully in the territory. See e.g., *Equality of Treatment (Social Security) Convention* 1962 (No. 118); *Migrant Workers (Supplementary Provision) Convention* 1975 (No. 143); *Migration for Employment Convention (Revised)* 1949 (No. 97). For rights limited to those lawfully in the territory: *Migrant Workers Convention* 1975 (No. 151).

25 United Nations, 'Analytical Study of the High Commissioner for Human Rights on the Fundamental Principle of Non-Discrimination in the Context of Globalization', Report of the High Commissioner for Human Rights, Commission on Human Rights, (E/CN.4/2004/40: paras 7-15).

26 The Preamble to the Universal Declaration notes that 'every individual and every organ of society … shall strive by teaching and education to promote respect for these rights and freedoms'.

States

Under international human rights law, States are the primary 'duty-bearers' of human rights which means that HRIAs of trade agreements must assess how the particular agreement affects States' obligations under human rights law. The expression of the obligations on States with regard to human rights differs from treaty to treaty, but in essence, international human rights law imposes dual obligations – namely an obligation to refrain from certain acts that violate human rights (freedom from the State) and an obligation to take certain steps to ensure human rights (freedom through the State). Thus, on the one hand, States should avoid interfering in certain spheres of life such as movement, expression, and access to essential goods and services; and on the other, the State should take certain steps to ensure that all individuals, irrespective of background, have access to the basic necessities for a life in dignity. This applies to all rights, whether civil, cultural, economic, political and social.[27]

Nonetheless, some commentators contest the role of the State as a proactive agent with positive duties to ensure human rights. Most notably, contemporary neo-liberal writers promote a vision of the free market and human rights that views State intervention in the form of redistributive justice as unnecessary constraints on individual freedom, personal wealth accumulation and free trade.[28] A recent publication by the US Heritage Foundation notes the following: '(w)hile it is not disputed that a certain amount of labor market regulation is necessary for a labor force to function well, these are not rights in the sense that they arise from the nature of man. They are entitlements that, when given the status of fundamental rights, replace individual choice and responsibility with a plethora of claims that result in a dependent society with a pervasive centralized state'. Similar claims are made in relation to the 'insidious' rights to education and to health.[29]

Such views are unsustainable from the perspective of international human rights law. For example, States parties to International Covenant on Civil and Political Rights (ICCPR) have undertaken obligations 'to respect' and 'to ensure' civil and political rights emphasizing not only obligations of forbearance but also obligations to ensure

27 United Nations, 'Report of the High Commissioner', Economic and Social Council (E/2006/86, para. 8). See ICCPR, Article 2(1); ICESCR, Articles 2(1) and 2(2).

28 See e.g. Randy Barnett, condemning social rights as an unjustifiable interference with personal flourishing, believes that 'the government of a good society should protect persons and their property from being used without their consent'. According to Barnett, the role of government is to protect 'each person's liberty rights to acquire, use, and dispose of resources in the world without violating the like rights of others': Barnett, R., 'The Right to Liberty in a Good Society', *Fordham Law Review*, 69, 2001, 1603-1615, at 1614-1615. See also Pipes who notes that 'the main enemy of freedom is not tyranny but the striving for equality': Pipes, R., 'Private Property, Freedom and the Rule of Law', *Hoover Digest*, 2 2001.

29 See: Heritage Foundation, 'Economic and Political Rights at the UN: A Guide to US Policy-Makers' (available at: http://www.heritage.org/Research/WorldwideFreedom/bg1964.cfm – accessed 1 September 2006).

the conditions necessary to enjoy rights.[30] Similarly, in relation to economic, social and cultural rights, ICESCR requires States both to avoid discrimination in relation to these rights as well as to take steps towards their progressive realization.[31] The Committee on Economic, Social and Cultural Rights has referred to a typology of obligations to clarify States duties, noting that States' parties to the Covenant must not only refrain from interfering with rights (the duty to respect), but also to prevent violations by third parties (duty to protect) and to take appropriate measures towards the full realization of rights (duty to fulfil).[32] The State duty to protect human rights from the actions of third parties included in the Committee's typology has important implications in the present context given the potential of third parties, particularly business enterprises, to affect the enjoyment of human rights in the context of trade. This duty to protect, as well as the duty of business enterprises to respect human rights, is considered in greater detail in the next sub-section.

The important factor to emphasize in the present context is the dual role of the State under human rights law – as a guarantor of freedom through forbearance as well as a provider, protector and guarantor of basic goods and services. In contrast to certain visions of human rights as only freedom from State intervention, an HRIA must consider the impact of a trade agreement on State's obligations both to refrain from interfering with human rights and to take proactive steps to protect and fulfil human rights. Consequently, an HRIA should measure the impact of a trade agreement on reducing State interference with personal liberties but also the impact on the State's capacity to take positive steps to fulfil human rights – for example, the impact of an agricultural trade agreement on the capacity of the government to provide subsidies to rural people living in poverty.

Business enterprises

An HRIA should also consider the responsibilities of non-State actors in the context of trade reform, in particular business enterprises. This is due to the fact that the main actors in international trade often tend to be trading enterprises which, given their comparative size and power, can sometimes have an impact on the enjoyment of human rights equal to and even greater than many States – as sponsors of medical research, suppliers of essential medicines, agricultural producers, providers of essential goods and services, employers and so on. The Special Representative of the UN Secretary-General (SRSG) on the issue of Human Rights and Transnational Corporations and other Business Enterprises, Mr. John Ruggie, makes the link between HRIAs

30 ICCPR, Article 2(1).

31 ICESCR, Article 2(1) and 2(2).

32 See for example: United Nations, 'The Right to the Highest Attainable Standard of Health', Committee on Economic, Social and Cultural Rights, General Comment No. 14, (E/C.12/2000/4: para. 33).

and business enterprises, identifying HRIAs as one means by which a corporation can undertake 'due diligence'.[33]

While the assessments he is referring to are assessments of planned corporate activities on the enjoyment of human rights, rather than of trade agreements, human rights impact assessments of trade agreements could provide a link to corporate due diligence. In particular, where an impact assessment of a trade agreement identifies potential risks to the enjoyment of human rights, the assessment could act as a trigger for relevant trading corporations to examine the need for undertaking their own impact assessments in the context of their specific trading activities. Moreover, examining the responsibilities of business enterprises in the context of undertaking HRIAs of trade agreements could be important in setting out recommendations to ensure that the future implementation of the agreement has a positive impact on human rights.

Considering the responsibilities of business enterprises in the context of HRIAs of trade agreements raises the question of the nature of the responsibilities of business enterprises with regard to human rights. Human rights instruments do not themselves make explicit mention of corporate responsibility for human rights.[34] Instead, as noted above, international law places the responsibility on States to protect human rights from the acts of corporations and other third parties.[35] Consequently, an HRIA should

33 The SRSG has relied upon the following definition of 'due diligence': 'diligence reasonably expected from, and ordinarily exercised by, a person who seeks to satisfy a legal requirement or to discharge an obligation'. The SRSG understands the term in a broad sense to mean: 'a comprehensive, proactive attempt to uncover human rights risks, actual and potential, over the entire life cycle of a project or business activity, with the aim of avoiding and mitigating those risks'. According to the SRSG, human rights 'due diligence' should include the adoption of a corporate human rights policy, a human rights impact assessment to consider the potential impacts of corporate activities before they begin, integration of the human rights policy through the company, including through training and leadership from management, and tracking performance through monitoring and auditing ongoing processes: United Nations, 'Respect, Protect and Remedy: A Framework for Business and Human Rights', Report of the Special-Representative of the Secretary-General on the issue of Human Rights and Transnational Corporations and Other Business Enterprises, Human Rights Council, 2008, (A/HRC/8/5: paras 59-63). The SRSG takes the definition of 'due diligence' from *Black's Law Dictionary* 8th Edition (2006): see *ibid.* footnote 47.

34 The preamble to the UDHR provides a starting point with its proclamation of the Declaration as 'a common standard of achievement for all peoples of all nations, to the end that every individual and every organ of society … shall strive by teaching and education to promote respect for' the rights in the Declaration. While the Covenants make no explicit mention of responsibilities of non-state actors, some other human rights instruments do refer indirectly to such responsibilities by placing obligations on States to ensure that the private actors, including enterprises, respect human rights. See e.g., ICERD, Article 5 – States must prohibit racial discrimination in relation to the right to access any place or service intended for use by the general public; CEDAW, Article 2(e) – States undertake to take all appropriate measures to eliminate discrimination against women by any person, organization or enterprise.

35 The ILC's draft articles on Responsibility of States for Internationally Wrongful Acts identify State responsibility for persons or entities that are not organs of the State but which are empowered by the

still place primary focus on the impact of trade agreements on the capacity of States to meet their human rights obligations. However, soft law instruments suggest some form of responsibility of business enterprises with regard to human rights. Most relevant, the International Labour Organisation's (ILO) Tripartite Declaration of Principles concerning Multinational Enterprises and Social Policy and the OECD Guidelines for Multinational Enterprises are international instruments directed at business enterprises which include general responsibilities on business enterprises with regard to human rights, although such responsibilities are not legally binding on business.

The UN Human Rights Council has been at the forefront in clarifying the human rights responsibilities of business enterprises. The SRSG on the issue of Human Rights and Transnational Corporations and Other Business Enterprises has developed a conceptual and policy framework to anchor the debate on human rights and business which stresses three principles: first, the State duty to protect against human rights abuses by third parties such as trading companies; second, the corporate responsibility to respect human rights, in the sense of doing no harm to human rights; and third, the right to access effective remedies.[36] In relation to the State duty to protect human rights, the SRSG observes that international law requires States to protect against abuse of human rights by non-State actors, including business enterprises, within the States' territory or jurisdiction. He acknowledges that there is disagreement on whether international law requires States to prevent traders from abusing human rights abroad, although recognizes the increasing pressure on States to take regulatory action to prevent their companies from abusing human rights overseas.[37]

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law of the State to exercise governmental authority as well as for private entities under a State's control: Draft Articles on Responsibility of States for Internationally Wrongful Acts, Articles 7 and 8.

36 Report of the Special Representative of the Secretary-General on the issue of Human Rights and Transnational Corporations and other Business Enterprises, *op.cit.*. For more discussion on the responsibilities of business enterprises with regard to human rights, see: Addo, M. (ed.), *Human Rights Standards and the Responsibility of Transnational Corporations*, Kluwer Law International, The Hague/London/Boston, 1999; Kamminga, M., and S. Zia-Zarifi (eds.), *Liability of Multinational Corporations Under International Law*, Kluwer Law International, The Hague/London/Boston, 2000; van Genugten, W.J.M., 'The Status of Transnational Corporations in International Public Law' in A. Eide, H.O. Bergesen and P. Rudolfson Goyer (eds.), *Human Rights and the Oil Industry*, Antwerp/Groningen/Oxford, Intersentia, 2000, pp. 71-89; Jägers, N., *Corporate Human Rights Obligations: In Search of Accountability*, Antwerp/Oxford/New York, Intersentia, 2002; all of which are cited in: van Genugten, W., 'Linking the Power of Economics to the Realisation of Human Rights: the WTO as a Special Case', in Kumar, C.R. and D.K. Srivastava (eds.), *Human Rights and Development: Law, Policy and Governance*, City University of Hong Kong, Hong Kong/Singapore/Malaysia, 2006, pp. 201-220; Clapham, A., *Human Rights Obligations of Non-State Actors*, Oxford, Oxford University Press, 2006.

37 *Ibid*., paras 18, 19. Van Genugten takes a stronger position and notes that it has now been established that corporations do not have liberty to choose whether they should comply with legal standards that were primarily addressed to States at least 'not when these standards are reflecting binding international law (*jus cogens*)'. See van Genugten, *ibid*., p. 207.

The SRSG derives a corporate duty to respect human rights – a responsibility not to infringe the rights of others – from the various soft law instruments mentioned above, such as the OECD Guidelines and the ILO Tripartite Declaration. In keeping with the approach in the UN human rights instruments, the corporate duty to respect applies to all civil, cultural, economic, political and social rights. This, the SRSG observes, constitutes a corporation's social licence to operate and may involve a requirement for corporations to take positive steps, such as in adopting a workplace anti-discrimination policy. In order to meet this duty, the SRSG has identified the requirement that business enterprises undertake steps to ensure compliance with national laws and also manage the risk of human rights harm by avoiding it. The steps to be taken depend on the context in which the enterprise is operating, its activities and the relationships with other entities associated with those activities.[38] Enforcement of the State duty to protect and the corporate duty to respect human rights requires access to functioning judicial and non-judicial grievance mechanisms.[39] The inclusion of judicial mechanisms appears to acknowledge that the corporate duty to respect could amount to a legal obligation, at least in some situations.

The methodology for an HRIA on trade agreements should therefore ensure that it examines not only States obligations but also the corporate duty to respect human rights. This is so despite the fact that the corporate duty to respect has been derived essentially from soft law instruments and that no international human rights instrument has yet explicitly recognized a legal obligation on business enterprises to respect human rights. Indeed, the purpose of the methodology is to identify and validate, *inter alia*, the cause-effect relationships resulting from possible changes in trade regulation, the behaviour of business enterprises that trade and, in turn, the enjoyment of human rights. The clarification of whether the results of an assessment have legal consequences for business enterprises is important, but should not be determinative. The methodology should be based on the assumption that a business enterprise might be persuaded to change behaviour, or a government might change a position in trade negotiations, on the basis simply of solid evidence of potential human rights abuse, irrespective of whether legal implications arise.

The international community

An HRIA should also consider the responsibilities of other States parties to trade agreements on the enjoyment of human rights in the country in question. States, particularly powerful and wealthy States, can affect the enjoyment of human rights in other States depending on how they negotiate trade agreements. A policy to provide food aid to countries irrespective of the delicate balance between food provision and rural development might affect food-security and the enjoyment of the right to ade-

38 *Ibid*., paras 25, 55.
39 *Ibid.*, paras 83-86.

quate food in the food importing country.[40] Decisions to maintain agricultural subsidies in one country could have drastic effects on global food prices affecting agricultural production and food security in countries. The liberalization of the temporary cross-border movement of health professionals can lead to a skills drain from poorer countries with consequent impacts on the right to health in both the home and host country.[41] At the same time, the inclusion of a Millennium Development Goal that seeks international cooperation to develop an open, rules-based, predictable, non-discriminatory trading and financial system with a focus on assisting participation of developing and least developed countries underlines the potential role for wealthier countries to use trade to lift people out of poverty.[42]

As is the case with the human rights responsibilities of business enterprises, in spite of the causal relationship between the acts of one State and the enjoyment of human rights in another State in the trade sphere, the extra-territorial reach of obligations under human rights treaties is far from clear.[43] In human rights instruments related to economic, social and cultural rights, extra-territorial responsibilities, to the extent that they exist, are generally phrased in terms of international cooperation and, on a simple reading of the treaty texts, do not appear to require any specific course of action by States parties.[44] The question therefore becomes less whether extraterritorial obligations exist and rather what their precise nature and scope is.[45] For example, Article 2(1) of the ICESCR offers little clarity in obliging States to undertake 'to take steps, individually and through international cooperation, with a view to achieving progres-

40 See e.g., United Nations, 'Globalization and its impact on the enjoyment of all human rights', Report of the High Commissioner, Commission on Human Rights, (E/CN.4/2002/54), which discusses the impact of the liberalization of agricultural trade on the enjoyment of human rights.

41 See e.g., United Nations, 'The right of everyone to the highest attainable standard of physical and mental health', Report of the Special Rapporteur on the Right of Everyone to the Highest Attainable Standard of Physical and Mental Health, General Assembly, 2005, (A/60/348), which focuses on the migration of health professionals and the 'brain drain'.

42 Millennium Development Goal 8, in particular Target 2 (available at http://www.un.org/millennium goals/global.shtml – accessed 19 January 2008).

43 General international law appears to recognize extra-territorial obligations of States which might be of indirect relevance to human rights law. In the area of environmental law, the *Trail Smelter* arbitration concerned the responsibility for air pollution generated in one State causing damage in a second State. The Arbitral Tribunal concluded that 'no State has the right to use or permit the use of its territory in such a manner as to cause injury … in or to the territory of another or the properties or persons therein'. While the case concerned environmental law, the principle of State responsibility towards persons in other territories appears relevant also to trans-boundary human rights problems: Trail Smelter Arbitration (U.S. v Canada) (1938 and 1941), 3 *UNRIAA*, (1905). It should of course be noted that in some cases the question of extra-territorial obligations is clear, such as the Genocide Convention, which has no territorial restrictions. See Coomans, F. and M. Kamminga, *Extraterritorial Application of Human Rights Treaties*, Intersentia, Mortsel, Belgium, 2004, p. 4.

44 ICESCR, Articles 2(1), 11(2), 15(4); CRC, Articles 4, 17, 23, 28; CRPD, Article 32.

45 Coomans and Kamminga, *op.cit.*, p. 4.

sively the full realization' of economic, social and cultural rights.[46] Given the general openness of these provisions, it would appear that international cooperation is promotional in nature, in the form of a best-endeavours duty rather than a justiciable or legally-binding obligation. Potentially, a refusal to cooperate internationally leading to human rights abuse might be a violation of a norm of international cooperation. However, international cooperation in favour of human rights also raises questions of national sovereignty and interference in the internal affairs of other States, which would tend to militate against international cooperation promoting anything other than general exhortations to promote economic, social and cultural rights.

Nonetheless, the Committee on Economic, Social and Cultural Rights has adopted a broad view of international cooperation as a legal obligation. Referring to Articles 55 and 56 of the UN Charter, the Committee has noted that international cooperation for development, and thus economic, social and cultural rights, is a legal obligation for States and plays 'the essential role' in facilitating the enjoyment of the rights under the Covenant.[47] In later General Comments, the Committee has elaborated upon this role. In relation to the right to food, the Committee has identified obligations on States to respect, protect, facilitate the right to food in other countries through, for example, facilitating access to food and the provision of food aid where necessary. According to the Committee, States should ensure the right to food is given adequate attention in international agreements. At the same time, the Committee has stated that States should refrain from food embargoes as well as using food as a tool of political and economic pressure.[48] Coomans and Kamminga argue that extraterritorial obligations under ICESCR might entail an obligation on States parties acting as members of international organizations such as the WTO not to deprive people in other countries of enjoyment of basic human rights by their acts as members of such organizations.[49]

The Advisory Opinion of the International Court of Justice (ICJ) on *The Legal Consequences of the Construction of a Wall in the Occupied Palestinian Territories*, identified responsibilities on Israel beyond the responsibilities it had as the controlling authority. There, the ICJ held that not only did Israel, as the occupying power, have obligations to respect the economic, social and cultural rights of individuals in the

46 Upon examination, it would appear that international cooperation is a means to an end rather than an obligation. Part IV of the Covenant provides some indication of the meaning of 'international cooperation'. The Covenant stipulates that 'international action …includes such methods as the conclusion of conventions, the adoption of recommendations, the furnishing of technical assistance and the holding of regional meetings and technical meetings for the purpose of consultation and study organized in conjunction with the Governments concerned' (ICESCR, Article 23); The primary means of international cooperation appears to be UN organs, their subsidiary organs and specialized agencies rather than individual governments (ICESCR, Article 22).

47 United Nations, 'The Nature of States Parties' Obligations: Article 2(1) of the Covenant', Committee on Economic, Social and Cultural Rights, General Comment No. 3, 1990, (paras 13, 14).

48 United Nations, 'The Right to Adequate Food (article 11)', Committee on Economic, Social and Cultural Rights, General Comment No.11, (E/C.12/1999/5: paras 36, 37).

49 Coomans and Kamminga, *ibid.*, p. 7.

Occupied Palestinian Territories (OPT), it also had 'an obligation not to raise any obstruction to the exercise of such rights in those fields where competence has been transferred to the Palestinian Authorities'.[50] The Court held that the actions of Israel had the effect of impeding the enjoyment in the OPT of the right to work, the right to health, the right to education and the right to an adequate standard of living.[51] The ICJ's Advisory Opinion provides support for the position that States do carry responsibilities to respect human rights beyond their own territories and where they have effective control.

Unlike ICESCR, ICCPR has a clearer domestic focus. Article 2(1) of the Covenant establishes that States Parties undertake to respect and ensure civil and political rights to all individuals within its territories and the ICCPR does not include any specific reference to international cooperation within its section on obligations. Nonetheless, the Human Rights Committee has noted that States parties must respect and ensure civil and political rights of 'anyone within the power or effective control of that State party, even if not situated within the territory of the State party'. Further, States are responsible for those within their power or effective control acting outside their territories, such as national forces in international peace-keeping or peace enforcement.[52]

In conclusion, while States are the primary duty bearers of human rights, other States have certain extra-territorial obligations, such as a duty to cooperate internationally, including in the context of trade, although the exact nature of what this entails is still unclear. An HRIA of trade agreements should therefore also consider the role of other States in an assessment. While the exact legal nature of these duties and their content is sometimes ambiguous, the dual legal-policy function of impact assessment de-emphasizes the immediate importance of strict legal definitions and places greater stress on the identification of the causal relationship between the acts of State and non-State actors and the enjoyment of human rights by individuals. To the extent that States and non-State actors have an impact on that chain of events, a human rights impact assessment should highlight those cause-effect relationships and make recommendations that optimize positive impacts and avoid negative impacts.

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50 *Legal Consequences of the Construction of a Wall in the Occupied Palestinian Territories*, Advisory Opinion of the International Court of Justice, para. 112, (available at: http://www.icj-cij.org/ – accessed 19 January 2009).

51 *Ibid*., para. 134.

52 United Nations, 'The Nature of the General Legal Obligation Imposed on States Parties to the Covenant', Human Rights Committee, General Comment No.31, (CCPR/C/21/Rev.1/Add.13: para.10). A recent review of the work of regional and UN human rights treaty bodies has summarized the current state of thinking on extraterritorial obligations as follows: first, there appears to be agreement that if a State exercises effective control over foreign territory, the human rights treaties to which it is party are applicable to its conduct in that territory; second, there is broad agreement that if a State exercises power and authority over persons by abducting or detaining them on foreign territory the human rights treaties to which they are party are applicable; third, there is no agreement among treaty bodies on the extraterritorial application of human rights treaties that do not fall into the first or second categories such as extraterritorial killings not preceded by arrest: Coomans and Kaminga, *op.cit.*, p. 6.

3 A PROPOSED FRAMEWORK FOR HUMAN RIGHTS IMPACT ASSESSMENTS

3.1 A rights-based approach to impact assessment

A human rights impact assessment is more than merely measuring the impact of trade agreements on human rights. Any framework for a human rights impact assessment should also ensure that the methodology protects and promotes human rights and promotes an environment that is empowering to both rights-holders and duty-bearers. So much is obvious, as a human rights impact assessment that itself abused human rights would be somewhat ironic. However, the approach also draws on the importance of procedure to human rights law – freedom of information, due process and procedural fairness, participation and so on. Drawing on rights-based approaches to development, the framework comprises four elements as follows:[53]

1. Human rights should be the explicit subject of a human rights impact assessment;
2. The process of the impact assessment should respect human rights;
3. The impact assessment should contribute to developing the capacities of 'duty-bearers' and 'rights-holders';
4. The impact assessment should involve human rights mechanisms and actors.

Each of these elements is explained in turn below.

3.2 Human rights should be the explicit subject of a HRIA

The first element of a human rights framework is that the assessment should analyze the impact of a policy on the enjoyment of human rights – in other words, human rights should be the subject of the assessment. Measuring the impact of trade agreements against human rights standards goes to the heart of what makes a particular assessment a 'human rights' assessment. Without explicit reference to human rights norms and standards, a human rights impact assessment (HRIA) would have no

53 United Nations, *The Human Rights Based Approach to Development Cooperation: Towards a Common Understanding Among UN Agencies*, United Nations Development Group, 2003 (available at: http://www.undg.org/?P=221 – accessed 27 January 2008). The UN Common Understanding identifies three attributes of a rights-based approach to development cooperation: first, all programmes of development cooperation, policies and technical assistance should further the realization of human rights as laid down in the Universal Declaration of Human Rights and other international human rights instruments; second, human rights standards contained in, and principles derived from, the Universal Declaration of Human Rights and other international human rights instruments guide all development cooperation and programming in all sectors and in all phases of the programming process; and, third, development cooperation contributes to the development of the capacities of 'duty-bearers' to meet their obligations and of 'rights-holders' to claim their rights. See also: United Nations, *Frequently Asked Questions on a Human Rights-Based Approach to Development*, Office of the High Commissioner for Human Rights, New York and Geneva, 2006, p. 35.

significant added value over social impact assessment.[54] For example, the impact assessment of the Thai Human Rights Commission referred to in the Introduction provides only brief references to some international and national human rights obligations on the Government and makes no assessment as to the impact of the proposed trade agreement with the US on specific rights or on the capacity of the State to meet its human rights obligations. This calls into question whether the assessment can be referred to as a human rights impact assessment given that the assessment makes no clear conclusion regarding impact on human rights.[55]

Ensuring that human rights are the subject of the assessment implies that certain factors are present. First, the assessment should explicitly refer to international human rights norms and standards and identify which human rights are potentially affected by the policy. At a minimum, the human rights framework should refer to the UN core human rights instruments. However, depending on the context, other instruments might also be relevant. For example, a methodology developed by the International Finance Corporation, UN Global Compact Office and the International Business Leaders Forum (the IFC Guide) to assist business enterprises in undertaking *ex ante* assessments of investment projects refers explicitly to UN human rights treaties as well as ILO instruments.[56] Conversely, some methodologies take a narrow approach focusing on only some instruments or rights. For example, a methodology developed by the Ecumenical Advocacy Alliance (the EAA methodology) to examine the impact of rice trade liberalization focuses specifically on the right to food, while leaving open the possibility to consider the impact on related rights as appropriate.[57] Given the broad nature of the impact assessments proposed in this dissertation, covering potentially all trade sectors, it is proposed that the human rights framework should include all the core UN human rights instruments as a baseline. Depending on the focus of the assessment, the instruments and the specific rights considered might be narrowed.

Second, the assessment identifies the individuals and groups affected by the policy – the 'rights-holders' – as well as the State and non-State actors in positions of power

54 Harrison, and Goller, *op.cit.*, p. 605.

55 The principal reference to Thailand's international human rights obligations appears at the end of the assessment where the Commission expresses its opinions. Those references are incomplete and do not inform the prior analysis. While the Commission considers that the negotiations threatened human rights in 'many ways', only three examples are given. National Human Rights Commission of Thailand, *Report on Results of the Examination of Human Rights Violations*, Ad-Hoc Coordinating Sub-Committee to Review and Examine the Establishment of the Thailand-United States Free Trade Area, on file with the author, p. 63.

56 International Finance Corporation (IFC), UN Global Compact Office and the International Business Leaders Forum (IBLF), *Guide to Human Rights Impact Assessment and Management: Road-Testing Draft*, June 2007, IFC and IBLF, 2007, pp. 62-64.

57 For example, the EAA studies also refer to impact on the right to health and the right to education even though their main focus is impact of trade policies on the right to food. Paasch, A., F. Garbers and T. Hirsch (eds), *Trade Policies and Hunger: The Impact of Trade Liberalization on the Right to Food of Rice Farming Communities in Ghana, Honduras and Indonesia*, Commissioned by the Ecumenical Advocacy Alliance, 2007, p. 55.

and responsibility – the 'duty-bearers'. The identification of rights-holders and duty-bearers is particularly relevant to human rights assessments given the legal paradigm of human rights and the correspondence between rights and duties, rights –holders and duty-bearers. Through identifying stakeholders as rights-holders and duty bearers, the assessment provides the means of moving beyond statements on outcome – for example, increased prices for essential medicines – to the identification of who might be harmed by that outcome and who is legally responsible to remedy the situation. The identification of whose rights are affected by the policy or project and who has responsibility to remedy any problems is fundamental to ensuring that the assessment meets its goals, whether to learn from past experience, avoid future abuse or build on past success.

Ideally, the methodology should include a non-exhaustive list of rights-holders and duty-bearers most closely associated with trade agreements. For example, the IFC Guide includes a much wider variety of stakeholders given the nature of business activities covering a mix of community members, workers, government and non-state actors and the Guide also provides guidelines on identifying other stakeholders.[58] In the context of trade agreements, the list of stakeholders is long, covering farmers, persons with HIV/AIDS and other conditions reliant on access to essential medicines, indigenous peoples and minorities, female and male workers, users of essential services, trading corporations, investors, representatives of government Ministries (such as Health, Agriculture, Foreign Affairs, International Trade), National Human Rights Institutions amongst others.

Third, the assessment sets out human rights indicators by which to measure the impact of a policy or project on the enjoyment of human rights. Indicators are tools for verifying positive impact or documenting failures to achieve expected impact.[59] When applied systematically on the basis of a clear framework, indicators provide the basis for making reliable and valid causal connections between the policy or project, the enjoyment of rights by individuals and the fulfillment of obligations by government and other stakeholders. Chapter II discusses human rights indicators in more depth. For present purposes, it is relevant to signal two issues. First, it is important to adopt a framework for indicators based on human rights norms and standards. For example, the EAA methodology fails to set out indicators on the basis of an explicit framework.[60] This ad hoc approach weakens the human rights analysis by obscuring the causal link between rights, standards, and the impact of the policy or project. Second,

58 IFC Guide, *op.cit.*, p. 40.

59 Andreassen, B.A. and H-O. Sano, *What's the Goal? What's the Purpose? Observations on Human Rights Impact Assessment*, Norwegian Centre for Human Rights, University of Oslo, Research Notes, 2004, p. 5.

60 The EAA methodology identifies three principal indicators of a violation of the right to food: first, the involuntary reduction of meals in terms of quantity; second, as an alternative, a deterioration of the food quality due to forced reduction in variety of food; and/or third, increase of health problems related to hunger among families, especially children. EAA, *op.cit.*, p. 28.

the framework should be useful and comprehensive without being unwieldy. Rights and Democracy, a Canadian-based human rights NGO, has developed a Research Guide incorporating one of the most sophisticated methodologies for human rights impact assessments that focuses on foreign investment projects (the Rights and Democracy Methodology). The methodology includes a 75 page list of questions in the Research Guide and structured according to the draft *Norms on the Responsibilities for Business and Other Transnational Corporations with Regard to Human Rights* and informed by UN human rights treaties and the work of treaty bodies.[61] When the methodology was tested in five countries, users highlighted the cumbersome and technical nature of the list of questions and a lack of any guidance on how to choose some questions over others.

Fourth, the assessment expresses its conclusions in terms of impact on the enjoyment of human rights and fulfillment of obligations, identifying people affected and attributing responsibility to various State and non-State actors. In this way, conclusions on human rights impact are not only a measurement of the enjoyment of human rights by individuals and groups, but also a comparison between what the government has committed to and what the government has done. The analysis often goes beyond this and attributes responsibility to those actors with the power to affect change such as various line-Ministries, local and provincial government, intergovernmental organizations and corporations, even if their legal human rights responsibilities strictly speaking might not always be clear.[62] For example, the EAA study analyzes the responsibilities of not only government but also the IMF and the World Bank as well as the extra-territorial obligations of other countries such as the US. The IFC Guide is directed specifically at businesses as 'duty-bearers'. Expressing conclusions in terms of enjoyment of rights as well as fulfillment of obligations provides a means of challenging and transforming institutions by first identifying and then addressing legal and administrative entities and the private sector as responsible agents for change, providing a way to confront the challenge of unequal power among stakeholders.[63]

Fifth, making human rights the explicit subject of the assessment also implies that the assessment frames recommendations to duty bearers in terms of their human rights

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61 Rights and Democracy, *Human Rights Impact Assessments for Foreign Investment Projects: Learning from Community Experiences in the Philippines, Tibet, the Democratic Republic of Congo, Argentina and Peru*, International Centre for Human Rights and Democratic Development, Montreal, Canada, 2007, p. 20.

62 EAA, *op.cit.*, pp. 12ff. Maassarani et al consider human rights impact assessments as a means to bridge the gap between uncertain official legal expressions of human rights responsibilities of corporations with practical responsibility for human rights on the ground: Maassarani et al, *op.cit.,* p. 136. Methodologies such as the IFC methodology are focused specifically on ensuring that corporations meet their human rights responsibilities and embed human rights in management practice. IFC, *op.cit.*

63 The Rights and Democracy methodology identifies shifting the power dynamic and measuring the gap between the legal norm and experience through clarifying the roles of duty-bearer and rights-holder as among the principal benefits of using human rights as a framework for impact assessment. Rights and Democracy, *op.cit.*, p. 16.

commitments and responsibilities. In doing so, the assessment helps to remedy past abuse as well as to embed human rights in future practice and achieve the transformative change necessary to avoid problems in the future. This is particularly relevant to *ex ante* impact assessments that seek to influence trade policy-making and trade negotiations with realistic recommendations to protect human rights in the short and long term. This step can itself become an instrument of mobilization, organizing stakeholders to follow-up on the assessment with related action to improve enjoyment of human rights and remedy abuse.[64] The inclusions of a step on monitoring can help to ensure follow-through on the assessment and maintain vigilance so as to avoid future issues arising.[65]

3.3 The process of the assessment should respect human rights

Human rights should not only be the subject of the assessment methodology, the assessment methodology itself should draw on human rights principles, seeking to promote human rights through the assessment process itself. This is an important element of approaching impact assessment from a human rights perspective – viewing the individual as both the central subject of the assessment as well as an active participant and beneficiary of it.[66] Accordingly, the following sets out the relevant human rights principles and how they relate to the process of impact assessment:[67]

a) *Universality and inalienability* – Human rights are the birthright of everyone everywhere in the world and they cannot be given up voluntarily or taken away. Consequently, the impact assessment should not allow or propose 'trade-offs' that would result in the violation of human rights. This principle is important, particularly, where a trade policy might benefit the majority and an assessor might be under pressure to justify human rights abuses in the interests of the greater good.
b) *Indivisibility* – Civil, cultural, economic, political and social rights are equal in status and cannot be ranked or placed in a hierarchy *per se.* Consequently, an impact assessment should not place greater emphasis on particular rights, such as civil and political rights, as a matter of course or out of a belief that some rights are more important or fundamental than others.
c) *Independence and inter-relatedness* – The realization of one right often depends wholly or in part on the realization of other human rights. Consequently, the impact

64 *Ibid.*, p. 27.
65 See e.g.: IFC Guide, *op.cit.*, pp. 52-53.
66 For example, the Declaration on the Right to Development, Article 2(1), states that: 'The human person is the central subject of development and should be the active participant and beneficiary of the right to development'.
67 The principles indicated are those identified by the UN Common Understanding on a rights-based approach to development cooperation, *op.cit.*, p. 2.

assessment should consider impact on related rights even where the primary focus of the assessment might be one or a limited number of rights.

d) *Non-discrimination and equality* – Everyone is born equal as human beings by virtue of the inherent dignity of the human person. Moreover, all human beings are entitled to enjoy human rights without discrimination of any kind, such as race, colour, sex, ethnicity, age, disability, language, religion, political or other opinion, national or social origin, property, birth or any other status. Consequently, an impact assessment should not exclude or have the effect of excluding individuals or groups from the assessment, nor favour certain individuals or groups without justification.
e) *Participation and inclusion* – every person and all peoples are entitled to active, free and meaningful participation in, contribution to, and enjoyment of civil, economic, social, cultural and political development in which human rights can be realized. While important, participation and inclusion goes beyond transparency and consultation. An impact assessment should seek the active, free and meaningful participation of rights-holders and duty-bearers in the assessment process so that the assessment itself provides a means of enhancing the enjoyment of human rights. The use of participatory assessment methodologies is an important element of respecting this principle.
f) *Accountability* – In its strongest form, duty-bearers, particularly States, have legal obligations to respect, protect and fulfil internationally recognized human rights, according to the commitments they have voluntarily undertaken and under customary international law. Other actors also carry moral and potentially legal responsibilities with regard to human rights. Aggrieved rights-holders have a right to a remedy in the case of proven abuse of rights. Moreover, the impact assessment process should also be accountable to rights-holders and other actors, sharing conclusions and recommendations for example, with a view to ensuring that the process respects human rights. The assessment should address concerns of participants, including through explicit reference in the assessment report where necessary.

The choice of the techniques for information gathering and analysis is particularly important for ensuring respect for human rights in the process of impact assessment. This tends to place emphasis on qualitative participatory techniques for information gathering and analysis. Participatory assessment methods help to give voice to individuals and groups and reveal how they perceive and live their rights, making them active participants in the assessment process and beyond, rather than passive objects of study. Meaningful participation in the assessment of a policy, such as a trade policy, requires not only information sharing but also the provision of the means for people affected by that policy to be heard, to have the opportunity to influence decision-making and

feel empowered by taking part in decision-making.[68] For example, the Rights and Democracy methodology places a strong emphasis on participation and empowerment, viewing communities themselves, rather than the assessors, as the generators of data, seeking to build capacity of communities to understand human rights and using the assessment tool as an instrument for community mobilization.[69] While participatory techniques are important, it is relevant to underline that qualitative techniques also have their limits when assessing trade agreements and assessment of policies generally. The geographic reach of trade policy makes intensive participatory techniques too costly and time-consuming to undertake meaningfully, and risks basing conclusions on specific information that should not be generalized to wider sections of the population. Similarly, an assessment of trade requires at least some quantitative economic and statistical analysis, although this should be complemented with qualitative community-level research. Consequently, a mixed quantitative and qualitative approach is more appropriate for human rights impact assessments of trade agreements. This will be discussed in greater detail in Chapter II.

3.4 The impact assessment should contribute to building the capacity of rights-holders and duty-bearers

A human rights approach defines relationships between individuals and groups as rights-holders with enforceable claims against State and non-State actors, which hold corresponding responsibilities towards the rights of those individuals and groups. An important element of that approach is to work towards empowering rights-holders to make their claims and building capacity of duty-bearers to meet their responsibilities.[70] Through empowering rights-holders and building capacity of duty-bearers, the impact assessment process can better address underlying issues of powerlessness which often lead to human rights abuse, exclusion and discrimination.[71] It ensures that the assessment process goes beyond merely assessing the situation, towards providing an enabling environment for the realization of human rights.

Capacity building can occur in a number of ways. The use of participatory assessment techniques can not only involve individuals and groups in the assessment but also raise awareness about human rights and how to claim rights. The Rights and Democracy methodology emphasizes the use of human rights education as a means of improving the assessment outcome itself, as well as helping to empower communities

68 Hunt, P. and G. MacNaughton, *Impact Assessments, Poverty and Human Rights: A Case Study Using the Right to the Highest Attainable Standard of Health*, Submitted to UNESCO, May 2006, pp. 33, 39.

69 Rights and Democracy, *op.cit.*, pp. 24, 25 and 27. For example, in the case study in the Democratic Republic of Congo, the assessor team found that human rights education became one of the most important outcomes of the research experience.

70 UN Common Understanding, *op.cit.*, p. 3.

71 CDS Swansea and Associates Edinburgh Resource Centre Ltd, *PRAMs: Linking Participation and Institutional Change*, A Background Working Paper on the Participatory Rights Assessment Methodologies (PRAMs) Project, draft, October 2002, p. 3.

with knowledge of their rights, to mobilize them to defend their rights in the future.[72] Rights and Democracy found that the assessment process itself mobilized actors who became more engaged in promoting human rights, both in the context of the project being assessed, as well as in the broader human rights cause. In the Argentina case study, participants moved on to prepare an *amicus brief* that was accepted for consideration by the International Centre for the Settlement of Investment Disputes. The group later went to share experiences with South African communities who were also responding to water privatization schemes.[73]

Participation and empowerment also extends to States and other actors that have human rights responsibilities. Improving the enjoyment of human rights relies in part on building understanding and capacity within the institutions responsible for change and assessments should seek ways to include these actors through education, technical cooperation, consensus-building, sharing of information and participatory engagement.[74] The IFC Guide includes steps on implementing a human rights management process monitoring, evaluating and reporting on the management process. As a means of ensuring the integration of the recommendations flowing from assessment, the methodology stresses building corporate human rights capacity through training of managers, conveying the message that vigilance about human rights is an integral part of effective management, and providing guidance on how to respond to allegations of human rights violations.[75] In this way, a human rights impact assessment of trade agreements could provide a unique way of giving trade practitioners, such as trade negotiators, representatives of trade ministries, members of international organizations working on trade, economists, and others, information on the relevance of human rights to their work. It can also provide a means of discussing the duty to respect human rights with representatives of trading corporations and with investors. Importantly, through positive engagement of duty-bearers, the human rights discourse potentially becomes less threatening and more persuasive.

3.5 The impact assessment should involve human rights actors

The fourth element of a human rights framework is the involvement of human rights actors. The term 'actors' is used to refer to organizations, institutions and mechanisms working in the field of human rights, such as human rights NGOs, national human rights institutions, academics as well as regional and UN human rights experts. The human rights methodology should seek ways to involve international human rights actors, in particular regional and UN human rights treaty bodies and the Special Rapporteurs of the Human Rights Council. For example, several UN Special Rappor-

72 Rights and Democracy, *op.cit.*, p.25; PRAMs, *op.cit.*, p. 9.
73 Rights and Democracy, *op.cit.*, p. 27.
74 PRAMs, *op.cit.*, p. 12.
75 IFC Guide, *op.cit.*, pp. 52-59.

teurs have considered the impact of trade agreements on human rights.[76] An HRIA could be undertaken to follow-up on the recommendations of these actors. Alternatively, assessors could provide Special Rapporteurs or treaty bodies with the results of an assessment as a means of following up and monitoring the extent to which the government is implementing the results of an HRIA. Further, the results of the HRIA could be forwarded to human rights actors working in the field as a means of strengthening follow-up to HRIA recommendations. An international human rights NGO specialized in work on human rights and trade, 3D Trade, Human Rights, Equitable Economy has provided information to various treaty bodies on the implications of trade agreements for human rights which treaty bodies have incorporated in concluding observations and recommendations to States parties.[77] In short, an HRIA should not only be based on the norms and standards of international human rights law: it should also make use of the mechanisms that have been established to strengthen implementation of those norms with a view to strengthening the methodology, and also strengthening the knowledge within those mechanisms about issues such as the way in which trade agreements that can affect the enjoyment of rights.

The HRIA should also involve national human rights actors. The Thai HRC assessment is striking in this regard in that it was the National Human Rights Institution that took the lead in assessing trade negotiations. This in itself is an important factor, bringing human rights actors into the trade arena, commenting on trade as a human rights issue and bringing a particular understanding and experience to trade negotiations. In bringing human rights actors into the areas of development, trade and business activities, a flow-on effect is that actors outside the strict bounds of the human rights field also become more familiar with the relevance of human rights to their activities. For example, during the Thai HRC assessment, meetings were held with trade negotiators and other officials during the assessment process, hopefully challenging their understanding of 'trade' by highlighting its human rights impacts and not only its economic dimensions. Ideally, this dialogue should also be a two way process so that 'experts' in different fields engage in discussions on protecting human rights, particularly the rights of those living in vulnerable and marginalized situations, breaking down somewhat artificial barriers between areas of law and distinctions such as 'trade' and 'non-trade' issues.

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76 See e.g.: United Nations, 'Mission to the World Trade Organization', Report of the Special Rapporteur on the Right of Everyone to the Highest Attainable Standard of Physical and Mental Health, Paul Hunt, Commission on Human Rights, 2004, (E/CN.4/2004/49/Add.1). United Nations, 'Mission to the World Trade Organization', Report of the Special Rapporteur on the Right to Food, Human Rights Council, 2008, (A/HRC/10/5/Add.2).

77 See e.g.: 'International Trade, Health and Children's Rights – Thailand December 2005', Briefing Note by 3D, Trade, Human Rights, Equitable Economy, to the Committee on the Rights of the Child, and the 'Information Note 3' by the same organization noting the recommendations of the Committee to the Government to ensure that trade agreements did not negatively affect the right to health of the child and requesting answers to questions on the impact of intellectual property protection on the right to health. (available at: http://www.3dthree.org/en/pages.php?IDcat=4 – accessed 6 January 2009).

4 ORIGINAL ASPECTS OF THE HUMAN RIGHTS FRAMEWORK

4.1 Two social impact assessment frameworks

This section explains why this thesis advocates applying the HRIA methodology set out above, through comparing the HRIA framework to existing Social Impact Assessments (SIAs) methodologies to identify areas of overlap and those aspects of HRIAs that are original. Perhaps as a result of the openness of the term 'social impact' and the diverse fields of practice, there is no single agreed framework for SIA upon which to base such a comparison. However, two SIA frameworks do provide recognized guidelines and principles which in turn provide a solid basis for analysis. The first of these frameworks is set out in the US *Guidelines and Principles on Social Impact Assessment* (the US Guidelines) that the US Interorganizational Committee on Principles and Guidelines for Social Impact Assessment developed in 1993 and revised in 2003.[78] The Interorganizational Committee developed the US Guidelines to give guidance to practitioners undertaking social impact assessment of projects in the context of the US *National Environmental Policy Act* of 1970 – arguably the origin of modern SIA.[79] The Interorganizational Committee revised the Guidelines in 2003 to take into account the need to undertake SIAs of policies as well as projects. The US Guidelines set out the overall goals of SIA, they define social impact, identify principles underpinning SIA and provide a ten-step process for undertaking them as well as guidance on indicators and data collection and analysis.

The second SIA framework is set out in *Social Impact Assessment: International Principles* of the International Association of Impact Assessment (the IAIA Principles).[80] The IAIA developed these Principles over a five year period as a living document to be modified over time on the basis of experience. In contrast to the US Guidelines, the developers of the IAIA Principles sought to create a framework with international relevance, a process found to be difficult in light of differing cultural, religious, social and economic contexts.[81] The IAIA Principles define social impact and describe the activities comprising SIA and then proceed to identify the core values of the community of SIA practitioners, drawing heavily on human rights. On the basis of these core values, the IAIA Principles set out principles for SIA. Rather than

78 The Interorganizational Committee on Principles and Guidelines for Social Impact Assessment, *Principles and Guidelines for Social Impact Assessment*, 1993 and revised 2003. The Interorganizational Committee on Principles and Guidelines for Social Impact Assessment, 'Principles and Guidelines for Social Impact Assessment in the USA', *Impact Assessment and Project Appraisal*, 21(3), September 2003, 231-250.

79 Vanclay F., 'Conceptual and Methodological Advances in Social Impact Assessment' in H.A. Becker and F. Vanclay, *The International Handbook of Social Impact Assessment: Conceptual and Methodological Advances*, Edward Elgar, Cheltenham, UK and Northampton, MA, USA, 2003, p. 1.

80 Vanclay, F., 'Social Impact Assessment: International Principles', *International Association of Impact Assessment*, Special Publication Series, No. 2, 2003, (the IAIA Principles).

81 IAIA Principles, *ibid*., p. 1.

develop specific guidelines, the IAIA Principles establish a framework for the later development of guidelines, stressing the importance of involvement of the community of SIA practice and the need not to impose guidelines from above.[82]

These two frameworks provide a solid basis upon which to compare SIAs with HRIAs. While there is no single SIA methodology, the US Guidelines grew out of the origins of SIA in US environmental legislation and have been recently revised to ensure their ongoing relevance. The IAIA Principles, while recent, have been developed in the context of the International Association of Impact Assessment which is widely recognized as the principal forum for discussion of impact assessment and the leading global authority on best practice in the area.[83]

4.2 Areas of overlap between human rights and social impact assessment frameworks

Five general areas of overlap exist between the HRIA framework identified in the previous subsection and the two SIA frameworks identified here. The first of these areas of convergence concerns the importance attached to public participation. The US Guidelines, for example, promote public involvement in all stages of the assessment, identifying and working with all affected individuals and groups throughout the assessment process, extending beyond the assessment to provide the foundation for subsequent monitoring of the policy or programme.[84] Similarly, the IAIA Principles recognize that decisions on projects and policies are not only the domain of experts but should also be acceptable to the community, while the assessment process should incorporate local knowledge.[85] The emphasis placed on participation in the SIA framework is very familiar to HRIAs, which seek to promote public participation in the process of undertaking the assessment, as well as assessing the impact of a policy on the right to take part in public affairs. Indeed, in both SIA and HRIA frameworks, participation is as important to the process of undertaking the assessment as it is to assessing the extent to which individuals and groups have a say in the decisions that affect them. An indication of the overlap between human rights and the SIA framework arises in the IAIA Principles themselves, which draws on human rights instruments as an internationally recognized guiding principle for participation, recalling Article 1 of the *Declaration on the Right to Development* by which every human

82 IAIA Principles, *ibid*, p. 8. One can only imagine that the IAIA Principles might be criticizing the US Guidelines. The need to include the community of practice in a participatory manner in the development of SIA principles and guidelines is stressed at several junctures. The IAIA Principles also criticize attempts to establish 'principles' of SIA practice which are not principles at all but rather guidelines – something that the US Guidelines do.

83 Becker and Vanclay, *op.cit.*, p. xi.

84 US Guidelines, *op.cit.*, pp. 243f.

85 IAIA Principles, *op.cit.*, pp. 5f.

person and all peoples are entitled to participate in, contribute to, and enjoy economic, social, cultural and political development.[86]

A second area of convergence, and one that is closely linked to public participation, is the importance that both the SIA and HRIA frameworks place on empowerment. Within the human rights framework, participation is not only an end – a right – in itself, it is also a means of empowering communities to influence the policies and projects that affect them, as well as building the capacity of decision-makers to take into account the rights of individuals and communities when formulating and implementing projects and policies.[87] A human rights framework treats individuals and groups not as passive objects of an assessment, but as holders of rights and active subjects in the assessment. Similarly, the IAIA Principles stress the importance of empowerment of local people and identify empowerment, capacity building and development of communities amongst the goals of SIA.[88] The US Guidelines identify the assessment process as a means of allowing participation of individuals and groups that are 'low in power' yet rarely included in the early planning stages of projects or policies even if potentially adversely affected.[89] While SIA and HRIA frameworks emphasize empowerment at the theoretical level, it is relevant to point out that SIA practice might not always follow theory, and human rights practitioners have criticized SIAs, as practiced by the World Bank and others, for the failure to confront the challenge of unequal power among stakeholders.[90]

A third area of convergence between the HRIA and SIA frameworks is the importance placed on examining impacts on individuals and groups. The HRIA framework addresses this through the principles of non-discrimination and equality. To respect these principles, an HRIA assesses the disparate impacts of policies and projects on individuals taking into account their sex, race, nationality, disability, language religion or any other status and examines the steps taken by the State to redress discrimination and to promote equality. Without referring explicitly to the principles of non-discrimination and equality, the SIA frameworks also highlight the need to ensure that research methods, data and analysis consider underrepresented and vulnerable stakeholders and populations as a matter of law.[91] The US Guidelines give examples of women, including unemployed women, adolescents, the elderly, the poor, persons with disabilities, minority groups and groups that are ethnically, culturally or racially distinctive, and occupational, cultural, political or value-based groups of relevance to the policy or

86 *Ibid.*, p. 6.

87 See e.g., the Rights and Democracy assessment framework that emphasizes communities as generators of data not objects of the assessment and the importance of shifting the power dynamic through assessment and providing capacity building for local communities. Rights and Democracy, *op.cit.*, pp. 16, 29.

88 IAIA Principles, *ibid*., pp. 2f.

89 US Guidelines, *ibid.*, p. 234.

90 Rights and Democracy, *op.cit.*, p. 16.

91 US Guidelines, Principle 5, Guideline 5(a), *op.cit.*, p. 237, referring to Executive Order 12898 on Environmental Justice (Executive Office of the President of the United States, 1994).

project under assessment.[92] The assessors should identify populations, describe and measure their social and cultural characteristics, incorporate the information into the baseline data sets and be alert to different social meanings of environmental impact.[93] The IAIA Principles also stress that a prime concern of the assessment should be to create awareness of the differential distribution of impacts among different people in society, particularly on vulnerable groups. In this vein, the Principles not only emphasize the need to undertake an assessment of who might win and lose as a result of a policy or project, but also encompass the enhancement of the position of women, minority groups and other disadvantaged or marginalized groups in society.[94] While HRIA and SIA frameworks place importance on examining impacts on individuals and groups, the particular framework for analyzing impacts based on discrimination and equality is specific to human rights law. This is a point of divergence between the HRIA and SIA frameworks which is discussed below.

Fourth, the SIA and HRIA frameworks are multidimensional in outlook and assess impact of projects and policies on a range of inter-related issues concerning the lives of people. Within the HRIA framework, this draws on the principles of interdependence and inter-relatedness of rights. For example, a right to health assessment might focus specifically on the right to health but would also examine effects on a range of other rights that are inextricably linked to the right to health in the context of the issue under examination, such as the right to food, right to water, the right to an adequate standard of living, freedom from torture and the right to liberty and security of the person.[95] HRIAs therefore provide a framework that considers the impact of a policy or project from many angles, giving depth and completeness to the assessment. SIA frameworks also consider social impacts of policies and projects in a wide context that includes community life, culture, property, political systems, the environment, health and well-being and fears and aspirations.[96] It is important to note that the range of issues considered within the term 'social impact' does not correspond precisely with internationally recognized human rights, nor do SIA frameworks rely on a distinctive set of civil, cultural, economic, political and social dimensions that can be applied equally to all assessments. The point emphasized at this juncture is simply that both frameworks consider impacts in a broad rather than narrow context.

A fifth area of convergence is in relation to monitoring. The legal nature of human rights leads inexorably towards the right to a remedy in the case of abuse of a right, and the monitoring of human rights situations to avoid violations arising and to record and provide compensation if they do arise. The SIA frameworks also emphasize the importance of monitoring. The process proposed in the US Guidelines refers to

92 US Guidelines, *ibid.*, p. 239.
93 *Ibid.*, p. 237.
94 IAIA Principles, *op.cit.*, p. 3.
95 Gay, R., *Mainstreaming Well-Being: An Impact Assessment for the Right to Health*, University of New South Wales, Paper on file with the author, 2008, pp. 22f.
96 IAIA Principles, *op.cit.*, p. 4.

development of a 'mitigation, remediation and enhancement plan'.[97] While any negative impacts of a policy or project should be avoided or minimized, where negative impacts are inevitable, then compensation to aggrieved people is necessary. Further, the US Guidelines include a step on developing a monitoring programme to observe deviations from the proposed action and related impacts, to track development and implementation of the project or policy and to react to unexpected impacts.[98] The IAIA Principles place less emphasis on accountability than the US Guidelines, but they do stress openness and accountability as values of SIA practitioners and emphasize the role of SIA to suggest mitigation and compensation measures on findings of negative social and environmental impacts.[99] While both the SIA and HRIA frameworks stress the importance of monitoring and accountability, the legal nature of human rights contrasts the legal accountability inherent in the HRIA framework with the softer monitoring and compensatory objectives of SIA frameworks.

4.3 Original aspects of the Human Rights Impact Assessment framework

There is quite clearly overlap between the HRIA and SIA frameworks. Areas of overlap are typical in the field of impact analysis and this is not necessarily a drawback. Overlap permits the sharing of experience and methods and adaptation of methodologies to particular areas of study such as child welfare, gender equity, health, social development, human rights and so on. However, in the present context, it is important to ask whether overlap between HRIA and SIA frameworks leads to the conclusion that the two frameworks are substantially the same. If they are, then the question arises whether HRIAs have any specific benefits for the socially progressive analysis of trade agreements. In spite of the considerable overlap between the two frameworks, there are at least six original aspects of HRIAs.

The first original aspect of the HRIA framework is its universal and comprehensive nature. HRIAs assess impacts in relation to a set of universally acknowledged and shared values and norms developed over 60 years and accepted by all States through ratification of international treaties. This is particularly helpful when assessments have an international context, as in the case of the assessment of trade agreements, as universal norms provide a level of cross-cultural and international legitimacy to the assessment framework and outcome. That universal framework is also comprehensive in its coverage, including not only social and economic aspects but also cultural, civil and political dimensions. SIA frameworks, on the other hand, have greater difficulty in identifying a comprehensive and universally-recognized normative framework and a common criticism of the social sciences is the tendency to employ different, even contradictory language, units of measurement, interpretation of indices and so on.[100]

97 US Guidelines, *op.cit.*, p. 244.
98 *Ibid.*, p. 248.
99 IAIA Principles, *op.cit.*, pp. 3f.
100 Barrows, C.J., *Social Impact Assessment: An Introduction*, Arnold, London and New York, 2000, p. 66.

Indeed, one of the challenges facing the development of the IAIA Principles was the difficulty in identifying principles with international relevance in light of differing cultural, religious, and socio-economic contexts. The heavy reliance on human rights in the core values of the IAIA Principles demonstrates how the human rights framework provides a unique means to address this challenge in social impact assessment.[101] The lack of a comprehensive set of civil, cultural, economic, political and social norms to frame SIA provides flexibility on the one hand, but also potentially leads to difficulties in comparing results and in contextualizing meaning by reference to an objective measure.

Two provisos are relevant to mention. First, the claim to universality can at times be more of a rhetorical device and tends to falter when considered up close. While by and large accepted in theory, the universality of human rights is not always accepted in practice, particularly among governments. For example, when Rights and Democracy undertook an HRIA in Tibet, direct questions on human rights could not be asked during the assessment due to the prevailing political situation and security concerns.[102] Alternatively, while the US Government would subscribe to the universality of human rights, its well-known resistance to economic, social and cultural rights might result in quite a different understanding of a human rights framework in practice. However, international human rights law is the strongest normative framework which claims universality and consequently still has value in developing an internationally relevant framework for impact assessment. Second, it is true that other internationally accepted frameworks of principles exist besides human rights law and these could also potentially provide legitimacy to SIA frameworks. These include the Millennium Development Goals (2000), the Copenhagen Declaration and Programme of Action (1995) and the Rio Declaration on Environment and Development (1992).[103] Nonetheless, these frameworks do not have the normative strength of human rights law, being more in the form of programmatic goals, nor do they make any specific claim to universality.

The area where SIAs do draw on an international framework of principles that compares to the human rights framework is in the environmental sector. For example, the IAIA Principles set out a list of eleven 'other guiding principles' drawn from environmental law.[104] Principles such as the 'polluter pays principle', the 'precautionary principle' or 'intergenerational equity' are particularly helpful in analyzing trade agreements. The principle of 'intergenerational equity' recognizes that activities

101 IAIA Principles, *ibid.*, p. 5.

102 Rights and Democracy, *op.cit.*, p. 26.

103 For example, the IAIA Principles refer not only to the Declaration on the Right to Development but also to the Rio Declaration. IAIA Principles, *ibid.*, p. 6.

104 The precautionary principle, uncertainty principle, intragenerational equity, intergenerational equity, recognition and preservation of diversity, internalization of costs, the polluter pays principle, the prevention principle, the protection and promotion of health and safety, the principle of multisectoral integration, the principle of subsidiarity: IAIA Principles, *op.cit.*, pp. 6f.

should be planned so that the needs of the present generation do not compromise those of future generations. Human rights law does not have an equivalent principle and tends to focus on the contemporaneous enjoyment of human rights. While the notion of 'progressive realization' does bring into play a temporal element, it does not normally include an overt intergenerational aspect. These principles parallel the benefits offered by the human rights framework to the analysis of trade agreements; however, their relevance and strengths are in the area of environmental analysis rather than social analysis. This underlines the fact that HRIAs are not intended to replace SIAs or environmental impact assessments. Rather, the frameworks are overlapping but distinct, with their own benefits and strengths.

Second, closely linked to the first benefit of HRIAs is the reliance on an objective standard as the standard of assessment. The use of an objective standard helps to give meaning to an assessment beyond the particular situation under study. The identification of a negative impact due to a policy or project means more than the subjective opinion of the assessor; it becomes a reliable conclusion that can be validated against an outside measure and compared with similar situations in other contexts. Without reference to an objective measure, the question arises as to where to locate the point of comparison. One possibility is to rely on the baseline or current situation as the point of comparison, which risks accepting the status quo uncritically – in other words, the project or policy is acceptable so long as it does not worsen current levels of standard of living The objectivity of the human rights framework assesses both the baseline situation as well as the future impacts. In this way, the current level of human rights enjoyment also comes under examination in the assessment and recommendations flowing from the assessment might relate not only to the policy or project but also to remedying current human rights abuses. In contrast, SIAs do not rely on an objective standard as a general rule, which leads to a tendency to take the baseline situation as the point of reference and as an acceptable measurement of standard of living, potentially leaving current human rights situations uncovered and even justifying a policy or project that could exacerbate them.[105]

Gay illustrates this difference in relation to an assessment of the impact of proposed changes to Slovenia's agricultural and food policies prior to adhesion to the European Union. She notes how the assessment indicates a risk of higher rural unemployment and negative impacts on health in an area that already had high levels of alcohol-related deaths. The impact assessment made a series of recommendations directed towards avoiding farm intensification and increased unemployment while avoiding consideration of the current problems affecting rural health. Gay notes that an HRIA would begin and end in a different place. An HRIA would consider the baseline situation in relation to international standards and consider whether existing ill-health and alcohol-related deaths resulted from failures on the State to realize the right to health or the prohibition on discrimination. Recommendations of the HRIA would not

105 Gay, *op.cit.*, p. 25.

only be directed towards avoiding a deterioration of the existing situation, but also identify pro-active steps seeking to change the baseline situation, with a view to moving towards the full enjoyment of the right to health.[106] Of course, there is nothing to stop an SIA from also assessing the baseline situation. However, by using an objective standard by which to measure impacts, HRIAs necessarily politicize the baseline situation rather than use the baseline as an acceptable situation. While an SIA might make recommendations to ensure that the future policy does not worsen the baseline situation, HRIAs assessment would make recommendations towards meeting the minimum standard, both now as well as in the context of future introduction of a policy.

Third, the human rights framework provides a more solid analytical framework to strengthen the interpretation of the results of an assessment. Take as an example the treatment of individuals and groups. As noted above, both SIA and HRIA frameworks seek to assess the disparate impacts of projects and policies on different individuals and groups. However, an HRIA draws on the decades of jurisprudence of national, regional and international courts and tribunals to help analyze the meaning of disparate impact. For example, human rights law examines whether the disparate impact observed is due to discrimination in law or in practice, whether there has been direct or indirect discrimination, whether an individual has a right to claim a reasonable accommodation as a result of the disparate impact, whether discrimination is justifiable, what steps the government should take to promote substantive equality, and so on. This in turn helps to analyze the underlying biases that might have led to the disparate impact arising and which actors have responsibility to rectify the situation. SIA frameworks do not have the same normative structure as a basis for analysis. Instead, the analysis appears to focus on identifying the distribution of impact among different people on the basis that no category of persons should bear the brunt of a policy or project; yet neither the US Guidelines nor the IAIA Principles provide clear guidance on how to interpret disparate impact.[107]

To illustrate the difference, while HRIAs rely on relatively clearly-defined notions of 'discrimination' and 'equality', SIA frameworks tend to mix references to equality with other less precisely defined terms such as 'fairness and equity'[108] or 'impact equity'.[109] The notion of 'equity', more familiar to international environmental law than human rights law, brings in an element of uncertainty and subjectivity to the analysis. Equity avoids the uniform application of general rules in all contexts. While equity is available as a means of moderating the law in the interests of fairness, it also tends to obscure decision-making due to its lack of clarity.[110] Reliance on equity could

106 *Ibid.,* p. 25.
107 US Guidelines, *op.cit.*, p.238; IAIA Principles, *op.cit.*
108 IAIA Principles, *ibid.*, p. 3.
109 US Guidelines, *op.cit.*, p. 238.
110 International Council on Human Rights, *Climate Change and Human Rights: A Rough Guide*, International Council on Human Rights Policy, Geneva, 2008, pp. 60f.

potentially justify a policy or project proceeding on the basis of the greatest good for the greatest number, a result that could well constitute an abuse of human rights and the prohibition on discrimination.[111]

Fourth, HRIAs limit the extent to which 'trade-offs' are possible between the greater good and the living conditions of individuals and groups, by providing clearer minimum thresholds to determine what impacts are acceptable or not. Policy-makers, particularly economists, observe that the introduction of a policy or project will often result in 'winners' and 'losers' and policy-makers will have to 'trade-off' various interests and compensate 'losers' as part of any reform process. However, human rights standards identify the minimum levels of civil, cultural, economic, political and social conditions for a life in dignity, below which it is unacceptable to go. Consequently, 'trade-offs' between 'winners' and 'losers' are not possible where the conditions of 'losers' go below that minimum threshold. This is particularly relevant to protect the situation of persons living in vulnerable or marginalized situations who might not always have a voice in decision-making processes and whose interests can easily be sacrificed in the interests of the majority or a more vocal minority. Interestingly, the IAIA Principles illustrate the relevance of using human rights to define the limits of policies and projects by including a principle 'that development processes that infringe human rights of any section of society should not be accepted'[112] and observing that some conceptualizations of SIA focus on 'protecting individual property rights, with clear statements of adverse impacts to ensure that individual rights are not transgressed'.[113]

A fifth original aspect is the fact that the human rights framework turns social imperatives into legal obligations, giving greater force to recommendations flowing from an assessment. Human rights law creates legal claims for individuals and groups which are enforceable against States. All States have undertaken legal obligations through the ratification of international treaties, some of which, such as the *Convention on the Rights of the Child*, have received almost universal ratification. The SIA frameworks do not carry the same legal weight. The previous section observed that both SIA and HRIA frameworks promote accountability. Yet, although an SIA might recommend compensation or a remedy to those aggrieved by the introduction of a policy or project, there is no guarantee of implementation. Indeed, one criticism of SIAs has been the lack of a legal framework which has sometimes weakened recommendations and resulted in failure to garner official support and acceptance.[114] HRIAs

111 International Council on Human Rights, *ibid*, pp 60f, quoting Dinah Shelton: '[D]ebate exists on the appropriate principles to determine equitable allocation, e.g. whether decisions should be based on need, capacity, prior entitlement, 'just deserts', the greatest good for the greatest number, or strict equality of treatment': Shelton, D., 'Equity', in D. Bodansky, J. Brunnée, E. Hey, *The Oxford Handbook of International Environmental Law*, Oxford University Press, Oxford, 2007, p. 653.

112 IAIA Principles, *op.cit.*, p. 6.

113 *Ibid*., p. 3.

114 Barrow, *op.cit.*, p. 10.

have the potential to take impact assessments a step further by locating conclusions and recommendations within the context of legal obligations that States have voluntarily undertaken. By relying on human rights law as a framework, the decision-maker is confronted by recommendations which, if ignored, could carry legal consequences, thus adding an additional incentive to take the assessment more seriously.

Of course, it is important not to exaggerate the legal consequences flowing from ratification of human rights treaties. The implications of ratification can differ from country to country and some countries require an additional legislative act for treaties to be legally enforceable. Further, the legal force of some rights, particularly certain economic, social and cultural rights, might be disputed in some countries. However, even where legal implications of human rights might be weak, phrasing analysis and recommendations in human rights terms can still provide greater moral force to social imperatives.[115] The eagerness with which businesses seek to avoid the label of human rights violator is an illustration of how human rights can be used to effect. In this sense, human rights language can give greater force to social objectives as the use of terms such as 'polluter' gives greater force to environmental objectives. Moreover, in many countries, the legal implications of human rights obligations, whether as a result of national law or international law, are real and this can help give additional force to the results of an assessment.

Sixth, as noted previously, the human rights framework can draw on human rights institutions and networks that can help implement recommendations of assessment and bring about transformative change. Human rights law brings with it international civil society networks, intergovernmental bodies as well as judicial, quasi-judicial and expert mechanisms and tribunals that provide a means of taking an assessment to a wider audience. The transnational human rights networks might not always be effective or appropriate for every human rights impact assessment. However, particularly where a human rights situation generates global interest, such networks can be employed to beneficial effect. By putting issues on the international agenda, claims of domestic human rights groups can be legitimated and national voices empowered, thus providing a transnational structure that pressures both from 'above' as well as from 'below' making transformative change based on the results of the assessment more possible, although not necessarily more probable.[116]

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115 To give an example, Correa, in an analysis of the impact of intellectual property protection in Bilateral Trade Agreements on access to health care, uses human rights to dramatic effect in his last sentence, warning that strengthened intellectual property protection limits progressive realization of the right to health. While not framing his analysis in human rights terms, he raises human rights in his last sentence to underscore the importance of the issue. Correa, C.M., 'Implications of bilateral free trade agreements on access to medicines', *Bulletin of the World Health Organization*, Public Health Reviews, 84(5), May 2006, p. 402.

116 See the study of the impact of transnational advocacy networks on sustainable domestic change in human rights developed by Risse and Sikkink in Risse, T. and K. Sikkink, 'The Socialization of Human Rights Norms', in T. Risse, S.C. Ropp, and K. Sikkink, *The Power of Human Rights: International Norms and Domestic Change*, Cambridge University Press, Cambridge, 1999, p. 5.

These are six ways in which the human rights framework could potentially add value to SIA frameworks, either by addressing some of the weaknesses indentified in those frameworks or by adding breadth and depth to them. The tentative nature of these factors is nonetheless important to underline. The potential for human rights law to add breadth and depth to the impact analysis of a policy or project is perhaps one of the strongest benefits of a human rights framework. Similarly, linking assessments with transnational networks of human rights practitioners offers considerable potential, particularly in the area of analysis of trade agreements given their international reach. However, as with SIAs, the theory and practice of human rights often differs, particularly in relation to the legal force of human rights norms, and so the extent to which human rights adds legal strength to an analysis might vary from case to case and country to country.

5 CONCLUSIONS

Chapter I has established a framework that underpins the methodology for HRIAs of trade agreements further developed in Chapter II. It clarifies some basic human rights concepts that are important elements of HRIAs, identifying the range of civil, cultural, economic, political and social rights that an HRIA should consider, as well as the range of actors – individuals, groups, States, business enterprises and the international community – who are affected by trade agreements and have responsibilities to protect human rights in the context of trade reform. Finally, the Chapter set out four basic elements of a human rights framework underlying HRIAs of trade agreements; first, human rights should be the explicit subject of a human rights impact assessment; second, the process of the impact assessment should respect human rights; third, the impact assessment should contribute to developing the capacities of 'duty-bearers' and 'rights-holders'; fourth, the impact assessment should involve human rights mechanisms and actors. The next Chapter applies this human rights framework to develop a methodology for HRIAs of trade agreements.

CHAPTER II
A METHODOLOGY FOR HUMAN RIGHTS IMPACT ASSESSMENTS OF TRADE AGREEMENTS

1 INTRODUCTION

Chapter II outlines a methodology for HRIAs of trade agreements. First, the Chapter identifies the main rules and principles included in trade agreements and proceeds to identify the trade sectors that have a more likely possibility of affecting human rights and the specific human rights thus affected. It should be noted that much of the discussion in these paragraphs focuses on the content and scope of WTO agreements, as opposed to bilateral or regional trade agreements. This section relies on WTO agreements as they have comprehensive coverage and broad multilateral reach and provide a useful means of illustrating the main rules and principles underlying trade agreements. However, the methodology developed in the rest of Chapter II is not restricted to WTO agreements. The growth of bilateral and regional trade agreements underlines the importance of extending the methodology for human rights impact assessments to non-WTO agreements. Each agreement is different and the methodology should be adapted to suit the specific requirements of each assessment exercise. However, the broad and comprehensive reach of WTO agreements provides an appropriate general basis upon which to design the general methodology in Part Two of this Chapter.

Section 3 of this Chapter sets out ten categories of potential ways in which trade agreements affect human rights. It is important to note that this is merely one repetitive way of classifying the impact of trade agreements on human rights – in a sense, it is somewhat artificial and even overlapping, but it is intended as a means of streamlining analysis in the impact assessment methodology. It is also important to note that the section presents impacts at the general level and so relies on the term impact on 'human rights' even if a trade agreement might affect only some human rights. For example, a positive impact on the right to education through liberalization of trade in educational services might be only one of many similar impacts and so will be expressed as 'trade agreements promote the growth and resources necessary for the progressive realization of human rights' – the use of the term 'human rights' is used as a means of generalizing and should not give the impression that trade agreements affect *all* human rights in such a way. The next section, section 4, sets out a step-by-step process for undertaking an HRIA of a trade agreement. The proposed process relies on the experience of existing methodologies for *ex ante* impact assessment of trade agreements which the section adapts in light of the specific requirements of the human rights framework developed in Chapter I.

The final section, section 5, discusses the collection and analysis of data, focusing on three issues. First, it considers the overall approach to data collection and analysis in light of the human rights framework underlying HRIAs of trade agreements. The focus of the human rights framework on subjective experience of human rights favours qualitative approaches, while the real world context of trade negotiations favours generalized quantitative methods. Consequently, the methodology requires a mixed-data or mixed-methods approach. Second, the section provides a means of identifying what quantitative and qualitative data should be collected in order to demonstrate the impact of trade agreements on human rights. This requires the identification of appropriate indicators. A conceptual and methodological framework is adopted and criteria are set to help identify the most appropriate indicators. Third, the section identifies the assessment techniques necessary to collect and analyze the data to clarify the various cause-effect relationships between the introduction of a trade measure and the impact on particular human rights. Rather than be prescriptive in the choice of assessment techniques for HRIAs, the section concludes by identifying some criteria for choosing the most appropriate techniques for a specific HRIA.

2 TRADE AGREEMENTS SUBJECT TO HUMAN RIGHTS IMPACT ASSESSMENTS

2.1 The content of trade agreements

A broad and increasingly large range of trade agreements exist at the multilateral, regional and bilateral levels. At the multilateral level, the *Marrakech Agreement Establishing the World Trade Organization* (the WTO Agreement) is the major pillar of trade agreements and source of international trade law today.[1] States have also negotiated regional and bilateral agreements. Trade agreements such as those forming the basis of trade in the European Communities and the North American Free Trade Agreement have taken on a significant role in the international regulation of trade. Other regions are also forming trading blocs, as demonstrated by the Dominican Republic-US -Central American Free Trade Agreement and negotiations on a Free Trade Agreement for the Americas. Regional trade fora such as the Asia-Pacific Economic Cooperation Forum established in 1989 have become important regional vehicles for promoting trade and economic cooperation and the European Union is increasingly negotiating Association Agreements with countries and regions which

1 The WTO Agreement consists of a short basic agreement with four annexes of numerous other agreements and understandings. Annex 1A contains thirteen multilateral agreements on trade in goods, including a revised version of GATT 1947. Annex 1B contains the *General Agreement on Trade in Services* (GATS) and Annex 1C contains the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (the TRIPS Agreement). Annex 2 and 3 include the *Understanding on Rules and Procedures for the Settlement of Disputes* and the *Trade Policy Review Mechanism* while Annex 4 contains several plurilateral agreements, such as the *Agreement on Government Procurement*, binding only upon those WTO Members that are party to the agreements.

feature the regulation of trade relations as a major pillar. Bilateral trade agreements have also taken on an important role, particularly in recent years with the stalling of current Doha Round of trade negotiations in the WTO.[2] Many of the rules and disciplines included in regional and bilateral trade agreements are similar to those negotiated in WTO agreements, although the strength of provisions or the extent to which they liberalize trade will differ between agreements and may include other issues such as rules on investment, competition policy and labour standards. This Chapter relies on WTO rules and principles as the basis of the methodology, supplementing those rules with material from other agreements, where necessary, to ensure a comprehensive coverage of trade measures that affect human rights.

The rest of this section sets out the main objectives, rules and principles of WTO agreements and illustrates in broad terms their relationship with human rights. HRIAs should consider in detail the cause-effect relationships between each of these rules and principles and human rights.

The preamble to the WTO Agreement indicates the aims and purposes of the WTO, recognizing that the relations of WTO members in the field of trade should raise standards of living, ensure full employment and a large and growing volume of real income and effective demand and expansion of production of and trade in goods and services. The Agreement states that these objectives should be pursued while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development and the integration of developing countries in the world trading system. While falling short of placing the enjoyment of human rights as an objective of trade relations among States in the WTO, the objectives of raising the standard of living, ensuring full employment and pursuing sustainable development parallel important human rights objectives such as the promotion of the right to an adequate standard of living, the right to work and the right to development.

The basic substantive rules and principles comprising international trade agreements cover the following broad areas:[3]

a) The prohibition of discrimination in the form of most-favoured nation treatment (MFN treatment) and national treatment;
b) Rules on market access;
c) Rules on unfair trade;
d) Exceptions;

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2 For example, the US have agreed or are currently negotiating bilateral trade agreements with Australia, Bahrain, Colombia, Chile, Israel, Jordan, the Dominican Republic, Malaysia, Morocco, Oman, Panama, Peru, the Republic of Korea, Singapore, the Southern African Customs Union, Thailand and the United Arab Emirates. See the website of the United States Trade Representative (available at http://www.ustr.gov/ Trade_Agreements/Bilateral/Southern_Africa_FTA/Section_Index.html – accessed on 22 January 2007).

3 This characterization has been adapted from Van den Bossche, P., *The Law and Policy of the World Trade Organization: Text, Cases and Materials*, Cambridge University Press, Cambridge, 2005, p. 39.

e) Special and differential treatment for developing countries; and
f) Procedural rules.

The rest of this section provides a short explanation of each of these six areas. The first area is the prohibition of discrimination. The prohibition of discrimination in international trade law is a primary means of combatting protectionism by promoting equality of trading opportunities for foreign goods and services and by ensuring that governments apply regulations of international commerce regardless of the origin of the goods, services or service providers. The prohibition on discrimination takes two forms – most favoured nation treatment and national treatment.

a) Most favoured nation (MFN) treatment requires a State to grant to every other State party to a particular trade agreement the most favourable treatment it grants to any other country with respect to the import and export of 'like' goods, services and service providers.[4] In other words, MFN treatment concerns equal conditions of competition between foreign goods, services and service providers.[5]
b) National treatment requires a State to treat foreign goods, services and service providers no less favourably than 'like' domestic, goods, services and service providers. Thus, while MFN treatment concerns competition between foreign goods, services and service providers, national treatment concerns competition between national and foreign goods, services and service providers.[6] The purpose of national treatment is essentially to ensure that internal protectionist measures do not frustrate tariff concessions granted at the border to foreign goods, services and service providers once goods or services are competing on the domestic markets.

The prohibition of discrimination in international trade law provides, in some ways, a point of departure for discussions on human rights and trade. However, while the two bodies of law prohibit discrimination and parallels between the two principles exist, they should not be confused in the methodology. Importantly, the human rights principle of non-discrimination is intrinsically linked to the promotion of substantive equality, evidenced by requirements under human rights law on governments to make reasonable accommodations for individuals and to promote affirmative action and special temporary measures for those who have traditionally suffered discrimination. The trade principle on the other hand, seeks to reduce discrimination against and

4 Article 1 of GATT states that 'any advantage, favour, privilege or immunity granted by any Member to any product originating in or destined for any other country shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other Members'. Article II of the General Agreement on Trade in Services states the MFN principles as follows: 'With respect to any measure covered by this Agreement, each Member shall accord immediately and unconditionally to services and service suppliers of any other Member treatment no less favourable than that it accords to like services and service suppliers of any other country.'
5 See e.g.: GATT, Article 1 ; GATS, Article 2 ; the TRIPS Agreement, Article 4.
6 See e.g.: GATT, Article III; GATS, Article XVII; the TRIPS Agreement, Article 3.

between foreign goods and services with a view to reducing trade protectionism and improving international competition but it does not seek to achieve substantive equality. For example, the trade principle of national treatment does not prohibit discrimination against nationals even if the national good, service or service provider might be in a weaker position comparatively, as can be the case in trade between poorer and wealthier countries.[7]

Rules on market access can be divided into four groups as follows:[8]

a) Rules on tariffs – Parties to trade agreements agree that tariffs or customs duties often constitute serious barriers to trade and so they negotiate mutually beneficial reductions of tariffs.[9] Once negotiations have agreed on reductions to or bindings of tariffs, tariffs may no longer be increased beyond the agreed level.[10] It is important to note however that trade agreements do not prohibit tariffs or customs duties as such.
b) Rules on other duties and financial charges – these include import surcharges, security deposits charged on imported goods, statistical taxes or financial charges imposed on processing imported goods by custom authorities.[11] Rules on these other duties and charges seek to ensure that States do not circumvent concessions on tariffs through the introduction of similar barriers.[12]
c) Rules on quantitative restrictions – subject to various exceptions, trade agreements avoid bans on the importation or exportation of goods or the use of quotas.[13] Trade agreements also ban quantitative restrictions in relation to trade in services, although generally with more flexibility. For example, in the WTO, quantitative restrictions are banned in those sectors where a WTO member has undertaken commitments to provide market access to foreign services and service providers.[14]
d) Rules on other non-tariff barriers – rules on market access also apply to transparency of trade regulations, technical regulations, standards, sanitary and phytosani-

7 United Nations, 'Analytical Study of the High Commissioner for Human Rights on the Fundamental Principle of Non-Discrimination in the Context of Globalization', Report of the High Commissioner, Commission on Human Rights, (E/CN.4/2004/41: para. 26).
8 Van den Bossche, *op.cit.*, p. 41.
9 GATT, Article XXVIII *bis*.
10 GATT, Article II(b).
11 Van den Bossche, *op.cit.*, pp. 436f.
12 GATT, Article II(b).
13 GATT, Article XI. Article XI(2) does however list certain exceptions to this rule, including export prohibitions or restrictions applied to prevent or relieve critical shortages of foodstuffs, import or export restrictions necessary to the application of standards or regulations for the classification, grading or marketing of commodities in international trade and import restrictions on agricultural or fisheries products necessary for the enforcement of certain government measures.
14 GATS, article XVI. However, quantitative restrictions can be imposed if such restrictions have been set out in the WTO Members schedule of market access commitments.

tary measures, customs facilities and government procurement practices.[15] Thus, for example, technical regulations on the manner in which a product is produced might effectively amount to a barrier to trade in certain cases and therefore disrupt access to markets. In certain situations, rules on non-tariff barriers might prohibit or regulate such measures.

Market access has important implications for people's lives, potentially both positive and negative. For example, increased market access through the lowering of tariffs can provide cheaper food or wider access to a range of essential services such as health care while providing jobs in export industries. On the other hand, the lowering of tariffs and other financial charges might restrict government revenue needed to protect public health, provide universal primary and secondary education or social security. These impacts have implications for the enjoyment of human rights, such as the right to adequate food, the right to health, the right to social security and the right to education. Bans on quantitative restrictions might obstruct the use of trade sanctions to punish States committing grave and systematic violations of human rights.

In relation to unfair trade, trade agreements cover areas such as anti-dumping as well as subsidies. First, dumping refers to the situation where a product is brought onto the market of another country at a lower than market price. For example, the highly subsidized agricultural sectors in the EU and the US produce a surplus of agricultural goods that can be sold at cheap prices in other markets. In certain situations, dumping can cause serious problems for the domestic industry, including through the flooding of the market with cheaper products, thus reducing the ability of local producers to compete effectively and ensure national food security, which in turn can affect the right to adequate food. In such cases, the importing country has room to impose anti-dumping duties on the dumped products, thus helping to restrict entry of those products.[16] Second, subsidies refer to financial contributions by a government or public body that confer benefits to producers or service providers.[17] Trade agreements generally prohibit export subsidies but not necessarily other subsidies. Where a subsidy has adverse effects on another country, the subsidising country should withdraw the subsidy or take steps to remove the adverse effects, otherwise the affected country might be authorized to impose countervailing duties to offset the effects of the subsidy. Agricultural subsidies in the EU and the US have attracted considerable attention for their distorting effects on agricultural production and the difficulties they pose to producers from other countries, particularly poorer countries, which cannot compete with the artificially low prices resulting from the subsidies. While low prices from subsidized food might lower food prices for consumers and improve the enjoy-

15 See e.g., The Agreement on Technical Barriers to Trade, the Agreement on Sanitary and Phytosanitary Measures, and the Agreement on Government Procurement.

16 GATT, Article VI, and the Anti-Dumping Agreement.

17 Van den Bossche, *op.cit.*, p. 42. GATT, article VI and the Agreement on Subsidies and Countervailing Measures are the principal means by which WTO disciplines regulate subsidies.

ment of the right to adequate food, it might also have adverse effects on local production and long-term food security, particularly in food-importing countries.

Trade agreements often allow certain exceptions to moderate the negative effects that trade liberalization might have on broader values and concerns related to human rights. Importantly, general exceptions permit countries to take measures in favour of a range of issues, including the protection of public morals and public order, as well as the protection of public life and health, the environment, privacy and national security.[18] While viewing public health, human life or the environment as exceptions to trade rules might not necessarily be the most appropriate way to ensure a positive relationship between trade reform and human rights issues related to trade, it nonetheless provides a level of openness to such issues.[19] WTO rules also allow certain exceptions to protect interests such as balance of payments safeguards, certain protections in times of emergencies, such as in the event of imports surges, and the pursuit of economic integration.[20]

Trade agreements, particularly WTO rules, also provide for special and differential treatment for developing countries that are parties to trade agreements, and in particular least-developed countries. Special and differential treatment permits slower rates of trade reform and provides for technical assistance to implement agreements. Most significant among these rules is the Generalized System of Preferences (GSP) which is a form of exception to MFN treatment. The exception, known as the 'Enabling Clause' allows developed country WTO members to apply tariffs to products from developing and least developed countries that are lower than the MFN level – namely the tariffs applied to products from developed countries.[21] The GSP has been a significant means of providing market access to products from developing and least developed countries, particularly in the agricultural sector. In this way, it could be said that the GSP, as a permitted exception to the prohibition on discrimination, is a parallel to affirmative action in human rights law, although, in comparison to human rights law where there is a legally binding obligation on States parties to provide temporary special measures or to make reasonable accommodations to combat discrimination, there is no legally binding obligation on WTO members to do so.[22] The GSP is also

18 GATT, Articles XX and XI; GATS, Article XIV; the Agreement on Government Procurement, Article XXIII; the Agreement on Trade-Related Aspects of Intellectual Property Rights, Article 27.

19 Office of the High Commissioner for Human Rights, *Human Rights and World Trade Agreements: Using General Exception Clauses to Protect Human Rights*, United Nations, New York and Geneva, 2005 (HR/PUB/05/5).

20 See GATT, Articles XII, XIX and XXIV; the Agreement on Safeguards and GATS, Articles V, X and XII.

21 See the 1979 Contracting Parties Decision on Differential and More Favourable Treatment, Reciprocity and Fuller Participation of Developing Countries (L/4903).

22 United Nations, 'Analytical Study of the High Commissioner for Human Rights on the Fundamental Principle of Non-Discrimination in the Context of Globalization', *op.cit.*. The report notes at paragraph 38 that: 'To use an analogy with the human rights principles of non-discrimination, the provision of trade preferences could be a positive measure to reduce global inequalities which in turn could provide a means of reducing inequality and discrimination at the national level'.

relevant to human rights as developed countries have used it as a vehicle for promoting human rights in developing countries, or put another way, to condition special treatment on human rights performance. In particular, the United States and the European Union have traditionally withdrawn preferences to countries with records of serious abuses of workers' rights.[23] The European Union also uses preferences as a means to encourage beneficiary countries to ratify human rights treaties.

Finally, trade agreements establish rules of a procedural nature on decision-making and dispute settlement. Three categories of procedural mechanisms are common in trade agreements, namely: dispute settlement; policy review mechanisms; and, political decision-making bodies. First, trade agreements differ in their approach to dispute settlement, with some covering resolution of disputes between States only, and others allowing private actors, such as a corporation, to bring a complaint against a State. The WTO's dispute settlement mechanism is the most elaborate example of an inter-state dispute mechanism, including procedures for consultations, dispute settlement, appeal and, where necessary, sanctions.[24] However, the WTO system does not allow for private actors to bring claims against States for non-fulfilment of treaty obligations. In contrast, some regional and bilateral agreements do include investor-to-state dispute mechanisms, such as the International Centre for the Settlement of Investment Disputes. Much of the discussion on human rights and trade has focused on how the trade dispute settlement mechanisms might deal with human rights in a future dispute.

Second, the WTO system includes a peer review mechanism in the form of the Trade Policy Review Body, through which Member States periodically review the trade policies of all WTO Members with a view to improving adherence to WTO agreements and strengthening the functioning and transparency of the multilateral trading system.[25] Such policy-review mechanisms might provide a future venue for the presentation of the results of HRIAs of a trade agreement. Third, trade agreements establish political bodies, in the form of Committees or Commissions, comprising representatives of the parties to the Agreement, with decision-making powers set out in the relevant agreement.[26] It is within these political bodies that trade negotiations,

23 See Dufour, S., Accords Commerciaux et Droits des Travailleurs, Les Éditions Revue de Droit de l'Université de Sherbrooke, 1998, 42-86, cited in: Howse, R., 'Back to Court after Shrimp/Turtle? Almost but not Quite Yet: India's Short Lived Challenge to Labor and Environmental Provisions in the European Union's Generalized System of Preferences', *American University International Law Review*, 18, 2003 1333-1380, p. 1337.

24 Understanding on Rules and Procedures Government the Settlement of Disputes (DSU).

25 Trade Policy Review Mechanism (Annex 3 to the WTO Agreement), para. A(i), 'Objectives'.

26 For example, within the WTO, the Ministerial Conference is the principal decision-making organ and has powers on any matter under any of the WTO agreements (See the Rules of Procedure for the Ministerial Conference, (WT/L/161)). The Ministerial Conference also has specific powers including to adopt authoritative interpretations of WTO agreements, to grant waivers, to adopt amendments to WTO agreements, decide on country accession and to appoint the Director-General of the WTO (WTO Agreement, Articles IX.2, IX.3, X, XII, VI.2 and VI.3). Otherwise, a General Council comprising representatives of all WTO Members deals with collective decision-making as well as a series of

such as the negotiations associated with the Doha Round, principally take place. The lack of formal civil society access to these bodies during trade negotiations has raised questions in relation to the right to take part in the conduct of public affairs.[27]

2.2 Sectors relevant to Human Rights Impact Assessments

Trade agreements cover trade in goods and services as well as trade-related aspects of intellectual property rights. In the WTO, for example, the three pillars of WTO agreements are the General Agreement on Tariffs and Trade (GATT) covering trade in goods, the General Agreement on Trade in Services (GATS) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In relation to trade in goods, GATT sets out broad principles, but a series of extra agreements provide special regulation of specific sectors. Thus the Agreement on Agriculture regulates trade in agriculture and the Agreement on Technical Barriers to Trade governs the use of technical regulations that could amount to non-tariff barriers to trade in goods. In relation to trade in services, while the main agreement of GATS sets out the general principles relating to all trade in services, with some minor exceptions, annexes to GATS set out specific commitments concerning market access with regard to a range of individual service sectors such as environmental services, education services and health-related and social services. Regional and bilateral agreements also regulate other sectors in addition to trade in goods and services and trade-related aspects of intellectual property rights, including issues such as investment and competition law.

On a broad view, all trade agreements have the potential to affect human lives and the public interest. For example, in helping to promote economic growth and employment, trade agreements help to provide the financial means needed to promote public health systems, provide universal and free education, and create employment. However, trade rules and principles in specific areas have attracted particular attention. Table II.1 provides an indication of the areas of overlapping concern to both trade agreements and specific public interest issues more closely related to human rights.

The first column, on the basis of the literature survey in section 3 that follows, identifies the eight trade sectors that are more often referred to in discussions on the impact of trade agreements on human rights. These trade sectors often appear as specific chapters in trade agreements or stand-alone agreements and should be the principal focus of HRIAs of trade agreements. However, it is important to emphasize that the methodology should adapt to the specific requirements of each assessment and

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specialized councils, committees and working parties, the most important of which correspond to the main agreements on goods, services and intellectual property protection (Namely, the Council for Trade in Goods, the Council for Trade in Services and the Council for Trade-Related Aspects of Intellectual Property Rights. WTO Agreement, Article IV.5.).

27 See e.g., United Nations, 'Analytical Study of the High Commissioner for Human Rights on the Fundamental Principle of Participation and its Application in the Context of Globalization', Report of the High Commissioner, Commission on Human Rights, (E/CN.4/2005/41).

a broader or narrower range of trade sectors might be relevant in some cases. The second column identifies potential effects of those trade sectors and trade measures on issues which could in turn have an impact on human rights.

Consequently, reading the first row, an agreement on trade in goods, such as GATT, includes trade measures seeking to reduce discrimination and remove barriers to market access, which in turn could affect economic growth and employment, which is important to the progressive realization of economic, social and cultural rights. GATT also includes general exceptions, such as the exception to protect human life and health, which could potentially be relevant to protect a human rights measure, for example, one related to the right to life or the right to health, in situations where human rights measures might otherwise be incompatible with trade measures.

It is important to emphasize that Table II.1 is designed essentially to identify those trade sectors which are more likely to affect the enjoyment of human rights, thus providing an indication of which trade agreements or chapters of free trade agreements an assessment should review in the initial stages of undertaking an HRIA. Section 3 below sets out in greater detail the sorts of impacts which might occur.

Table II.1 – Trade sectors more relevant to human rights

Trade sector	Issues relevant to HRIAs
Goods generally (e.g. GATT)	Reduction in discrimination in trade and improved market access could improve economic growth and employment in import and export industries, in turn providing financial resources for promotion of human rights, particularly economic, social and cultural rights (ESCRs). Similarly, special and differential treatment for developing countries could help increase trade in goods from poorer countries, potentially having positive impacts on human rights if accompanied by appropriate measures. Exceptions include protection of public morals and human life and health, which could potentially cover protection of human rights such as the right to life and health.
Agricultural trade (e.g. WTO Agreement on Agriculture)	Increased market access can promote the availability and accessibility of food (right to food); special and differential treatment can promote rural development but high barriers to trade in some wealthy countries can exacerbate poverty, threaten rural livelihoods (right to an adequate standard of living); food aid can provide food but damage sustainability of food production in the longer term (right to food).
Technical standards (e.g. WTO Agreement on Technical Barriers to Trade)	Agreements on technical standards include regulation of standards that might affect human health and safety (right to health); such agreements might also regulate standards relevant to human rights such as codes of conduct for business promoting corporate social responsibility codes (corporate duty to respect), human rights codes for business, social labels for goods and services promoting fair trade (corporate duty to respect); the regulation of standards also contributes to transparency in government regulation and therefore good governance (potentially positively affecting civil and political rights).

Health and safety measures (e.g. the WTO Agreement on Sanitary and Phytosanitary Measures)	Agreements regulating health and safety measures relating to trade can affect food safety as well as affect human life and health from plant or animal-carried diseases (potentially affecting right to food, right to health).
Trade in services (e.g. GATS)	As with trade in goods, reduction of discrimination and increased market access in services can create economic growth and employment with flow-on effects for progressive realization of ESCR in light of appropriate policies. GATS promotes market access and non-discrimination in 12 service sectors including educational services, health-related and social services, environmental services, communication services, recreational, cultural and sporting services which in turn can affect access to essential services (potentially affecting policies related to human rights such as universal access to essential services eg right to health, right to education, cultural rights).
Intellectual property protection (e.g. the Agreement on Trade-Related Aspects of Intellectual Property Rights)	Regulation of the grant and use of patents on pharmaceuticals can affect access to essential medicines (right to health), regulation of plant varieties and patents related to traditional knowledge can affect the cultural heritage and traditional knowledge of indigenous peoples and local communities (cultural rights, right to an adequate standard of living), patenting of plant varieties and seeds can affect food security (the right to food); copyright over educational materials can affect access to educational materials (right to education).
Government Procurement (e.g. the Agreement on Government Procurement)	Government procurement can be used to favour businesses run by individuals living in disadvantaged or marginalized communities or situations, but trade regulation of government procurement could treat such special measures as trade-discriminatory if adequate protections are not included in such agreements (affecting human rights principles of non-discrimination and equality).
Investment liberalization (e.g. Chapter 11 of NAFTA)	Investment agreements can increase investment in basic infrastructure and services which, accompanied by appropriate regulations, could affect progressive realization of ESCR; unsustainable investment or investment without proper national frameworks to protect human rights could have a negative impact on human rights (eg lowering of workers' rights or investment in polluting industries could affect the right to health); strengthened investor rights should be balanced with efforts to promote corporate social responsibility (corporate duty to respect human rights).

3 TEN CATEGORIES OF IMPACT OF TRADE AGREEMENTS ON HUMAN RIGHTS

The debate on the impact of trade agreements on human rights has produced an impressive array of academic, non-governmental and inter-governmental material which has considered the question from many angles. Much of the earlier work focused on the effect that trade agreements might have on a State's capacity to impose trade sanctions on a human rights violating State, such as Myanmar, or against specific

goods produced with child labour or forced labour. The debate then broadened and focused more closely on the impact of trade agreements on human rights-related issues at home, such as food security, access to medicines, access to essential services, cultural diversity, and the protection of indigenous peoples' traditional knowledge, amongst other areas. Some commentators criticized trade institutions and trade negotiators for their perceived lack of civil society participation, while others observed a correlation between free markets and strengthened respect for the rule of law.

This section groups the potential impacts of trade agreements on human rights into ten categories to help systematize the process of impact assessment of trade agreements. The grouping into ten categories has been achieved through synthesizing the now considerable literature on 'human rights and trade' and, through the use of judgment. Such a categorization is of course somewhat artificial. There are countless ways that the literature could be synthesized and this represents only one way. Moreover, there could potentially be other potential impacts of trade agreements on human rights which the existing literature has not yet considered – potentially raising further categories of impact. Further, the level of generality necessary to reduce impacts into only ten categories risks over-simplifying complex cause-effect relationships.

Nonetheless, the categorization provides a means of clarifying a rich and complex debate and a way to structure analysis of the impact of trade agreements on human rights in HRIAs. It identifies both potentially positive as well as potentially negative impacts of trade agreements on human rights. It also includes impacts arising at different levels: the strictly legal level (such as legal conflicts); the policy level (such as impact on policies to promote the progressive realization of economic, social and cultural rights); the process level (for example, the openness of trade institutions to civil society participation); as well as the philosophical level (for example, the compatibility of 'values' inherent in certain trade treaties and in human rights treaties). It need not be adhered to rigidly and can be adapted to specific HRIAs as required.

Finally, as noted in the introduction, the general term 'human rights' is used to mean one or any of the civil, cultural, economic, political or social rights recognized in international human rights law; however, it is not meant to suggest that trade agreements affect *all* of those rights, either potentially or in reality. The use of the general term 'human rights' leaves open the possibility of each HRIA to specify which particular rights are affected by the trade agreement under examination.

3.1 Trade law complements human rights law

Commentators have drawn on the common philosophical and historical roots of trade law and human rights law to demonstrate their complementarity. Philosophically, the Enlightenment has strongly influenced both trade and human rights law and several commentators draw on authors such as Adam Smith, David Ricardo, Thomas Paine, Imanuel Kant, Amartya Sen, John Rawls and even Karl Marx to demonstrate the link

between free markets and individual freedom.[28] Historically, commentators often observe that both bodies of law developed in the context of the post-War reconstruction effort as a means of avoiding the tyranny and economic recession that led to the War.[29] Commentators note the common objectives of the two regimes, referring to the Preamble to the WTO Agreement that recognizes that trade relations should be conducted with a view to raising standards of living, ensuring full employment, and furthering the objective of sustainable development.

Accordingly, the result is two-fold. First, trade agreements promote human rights. For example, Cottier, in proposing the need for further research into the way that trade agreements support civil and political rights, gives the example of the European Union which he says began with a functionalist approach to trade liberalization which has today evolved into a constitutional framework supportive of democracy, political stability and respect for human rights in an open European society.[30] He suggests further research is needed to examine the effect that open trade has on advancing personal liberty, freedom of information and freedom of expression and the advancement of political rights.[31] Moreover, to the extent that trade agreements promote more global economic transactions, they can contribute to the enforcement of human rights by increasing the contact between citizens of oppressive regimes and rights-respecting regimes, in turn promoting increased calls for political rights.[32]

Commentators also note that trade liberalization can promote respect for economic and social rights. Trade agreements can reduce barriers facing people living in poverty, empowering them to participate in trade and providing the economic means of lifting themselves from poverty.[33] While the evidence is not consistent across countries and sectors, trade liberalization can help combat discrimination against women, allowing women to acquire new skills and higher income, move from unpaid household and subsistence agriculture to the paid economy, and achieve a level of economic independence.[34] Studies note that trade liberalization has generated employment opportunities for women in export-oriented non-traditional agriculture such as cut flowers and

28 See e.g: Petersmann, E., 'Theories of Justice, Human Rights and the Constitution of International Markets', *Loyola of Los Angeles Law Review*, 37, 2003-2004, 407-459; Anderson, R.D. and H.Wager, 'Human Rights, Development, and the WTO: The Cases of Intellectual Property and Competition Policy', *Journal of International Economic Law*, 9(3), (2008), 707-747; Sen A., *Development as Freedom*, Oxford University Press, Oxford, 2001, p. 26.

29 Cottier, T., 'Trade and human rights: A Relationship to Discover', *Journal of International Economic Law*, 5(1), 2002, 111-132.

30 *Ibid.*. See also Anderson and Wager, *op.cit.*, p. 708.

31 Cottier, *ibid.*

32 Garcia, F.J., 'The Global Market and Human Rights: Trading Away the Human Rights Principle', *Brooklyn Journal of .International Law*, 25, 1999, 51-97, p. 59.

33 Trachtman, J.P., 'Legal Aspects of a Poverty Agenda at the WTO: Trade Law and 'Global Apartheid', *Journal of International Economic Law*, 6(1), 2003, 3-21.

34 Williams, M., *Gender Mainstreaming in the Multilateral Trading System*, A Handbook for Policy-Makers and Other Stakeholders, New Gender Mainstreaming Series on Development Issues, Commonwealth Secretariat, 2003, pp. 18-23.

in textiles and clothing. For example, one study notes that in South East Asia, women comprise 80 percent of the workforce in Export Processing Zones (although it is important to note that employment opportunities alone do not amount to improvements in human rights and much also depends on the conditions of employment, respect for an adequate minimum wage, health and safety in the work place and so on).[35]

Second, human rights may promote the objectives of trade agreements. For example, trade liberalization and trade agreements rely on respect for procedural human rights related to the rule of law and the effective functioning of transparent and impartial administrative and judicial procedures. Commentators have observed that the trade policies of a corrupt government that tolerates and supports lawlessness and a corrupt private sector inevitably leads to a distorted and highly insecure market.[36] Similarly, respect for democratic governance cannot allow an important segment of the population to be left aside by unfair trade practices.[37] Cottier and Khorana argue that respect for freedom of expression is an essential factor in supporting well-functioning markets based on access to information and stress the need for only very limited restrictions on freedom of expression, for example, in the case of proven ill-will in making commercial statements: 'credible and perfect information plays a crucial role' in ensuring that markets function.[38] At the same time, some commentators argue that the free market needs a functioning welfare state, through the promotion of economic, social and cultural rights, to compensate losers. A joint ILO/WTO report observes that the effect of trade openness on employment differs significantly across countries and an accompanying policy framework to facilitate social protection, education, redistribution, and transition towards a more open trading system, is particularly important.[39] Moreover, failure to respect human rights, through, for example, the use of forced labour, obstructs voluntary participation in markets and therefore distorts their proper functioning.[40]

35 Randriamaro, Z., *Gender and Trade*, Overview Report, Bridge: Development-Gender, Institute of Development Studies, University of Sussex, 2006, p. 16.

36 Howse, R., and M. Mutua, *Protecting Human Rights in a Global Economy: Challenges for the World Trade Organization*, Rights and Democracy, 2000.

37 Cottier, *op.cit.*

38 Cottier, T., and S. Khorana, 'Linkages between Freedom of Expression and Unfair Competition Rules in International Trade: The *Hertel* Case and Beyond', in Cottier, Pauwelyn and Bürgi, *op.cit.,*, p. 247.

39 International Labour Office/World Trade Organization, *Trade and Employment: Challenges for Policy Research*, A Joint Study of the International Labour Office and the Secretariat of the World Trade Organization, WTO, Switzerland, 2007.

40 Brown, D., A.V. Deardorff, R.M. Stern, *Pros and Cons of Linking Trade and Labor Standards*, Discussion Paper No. 477, School of Public Policy, University of Michigan, 2002, (available at: http://fordschool.umich.edu/rsie/workingpapers/Papers476-500/r477.pdf – accessed 28 December 2008).

3.2 Trade agreements promote the growth and resources necessary for the progressive realization of human rights

Taking the complementarity argument a little further, commentators make the claim (albeit often only in passing when discussing human rights), that the economic growth and employment resulting from improved market access for developing country goods and services to industrialized countries, and the promotion of investment in trade-oriented industries, provides the conditions for capital formation necessary to achieve free education, a universal health care system, full employment, accessible and adequate food, and social safety-nets; in other words, the progressive realization of economic, social and cultural rights.[41] In addition, trade agreements promote international cooperation and can be important tools for development that potentially provide a more sustainable alternative to international cooperation through development assistance – trade not aid.[42]

Two provisos are necessary at this point. First, there might not always be a correlation between trade agreements and increased economic growth and employment. Evidence suggests that generally there is a positive relationship between trade openness and growth.[43] Nonetheless, where free trade moves jobs to destinations where production is cheaper, where trade agreements lower tariffs and therefore government revenue for social programmes, where trade agreements increase imports in relation to exports, balance of payments problems might arise and free trade might reduce

41 See e.g., Van Genugten, W., 'Linking the Power of Economics to the Realisation of Human Rights: The WTO as a Special Case', in Kumar, C.R. and D.K. Srivastava (eds), *Human Rights and Development: Law, Policy and Governance*, City University of Hong Kong, Hong Kong/Singapore/Malaysia, 2006, pp. 201-220; Cottier, 'A Relationship to Discover', *op.cit.*; Anderson and Wager, *op.cit.*, p. 708; The report of the World Commission on the Social Dimensions of Globalization which notes that 'wisely managed, [the global market economy] can deliver unprecedented material progress, general more productive and better jobs for all, and contribute significantly to reducing world poverty': International Labour Office, 'A Fair Globalization – Creating Opportunities for All', World Commission on the Social Dimensions of Globalization, International Labour Office, Geneva, Switzerland, February 2004, p. x. Similarly, the UN High Commissioner for Human Rights noted in 2002 that 'In a general sense, the more efficient supply of services in any sector can promote economic growth and development, and therefore could provide the economic means needed to promote human rights': United Nations, 'Liberalization of Trade in Services and Human Rights', Report of the High Commissioner, Sub-Commission on the Promotion and Protection of Human Rights, (E/CN.4/2002/9: para. 39); Sykes, A., 'International Trade and Human Rights: An Economic Perspective', in Abbott, Breining-Kaufmann, Cottier, *op.cit.*, pp. 69-90.

42 See e.g., Cottier, 'A Relationship to Discover', *ibid.*; Anderson and Wager, *ibid.*, p. 708, 712.

43 For example, recent study on trade openness from 1950-1998 demonstrated that countries that liberalized their trading regimes experiences annual growth rates about 1.5 percent higher than prior to liberalization: Wacziarg, R. and K. Horn Welch, 'Trade Liberalization and Growth: New Evidence', *The World Bank Economic Review*, 22, 2008, 187-231. See also: McCulloch, N., L.A. Winters and X. Cirera, *Trade Liberalization and Poverty: A Handbook*, Centre for Economic Policy Research, United Kingdom, p. 24, which observes that: 'although trade openness has not been unequivocally linked to higher growth, it has certainly not been identified as a hindrance'.

government capacity to meet obligations in relation to human rights, at least at some stage of the trade reform process.[44] Further, economic growth and employment might not be spread evenly or might change over time. The recent joint ILO/WTO study on 'Trade and Employment' observes that trade reform generally requires some restructuring of the economic activity that can lead to job losses and closures in some parts of the economy and increased production and employment in other areas in the same country. The report concludes that in the short term, impacts might be positive or negative, depending on country specific factors such as the structure of the labour market, while in the longer term positive overall impacts are expected in terms of the quantity of jobs created, wages-earned, or a combination of both.[45]

Second, there is no automatic correlation between economic growth and employment, when it does occur, and the progressive realization of human rights. Where economic growth concentrates development in certain parts of a country – regions inhabited by ethnic majorities, urban areas, coastal areas – and not in others, social disparities might increase, leading to inequality, discrimination and denial of economic, social and cultural rights. Failure to address traditional patterns of discrimination, such as discrimination against women, might result in economic growth favouring powerful groups and individuals, exacerbating rather than diminishing human rights abuses. Similarly, increased employment might not automatically lead to increased respect for rights in the workplace where States do not have adequate labour legislation. Bartels states that while the relationship between trade, economic growth and improvements in welfare are commonly made at a general level, the mutual supportiveness of trade and social protection is ambiguous at best.[46] Sykes on the other hand undertakes an economic analysis and concludes there is a positive link between trade, wealth creation and respect for human rights, although he admits that tensions could arise.[47]

3.3 Trade agreements can breach human rights in practice

Trade agreements might lead to regressions in the enjoyment of human rights in practice, such as long-term job loss, food-insecurity, unacceptably high prices for essential medicines or school books, reduced access to essential services for the poor, restrictions on cultural protections, and failure to respect the cultural heritage of indigenous and local communities. Two provisos are important to highlight at the

44 United Nations, 'Globalization and its Impact on the Full Enjoyment of Human Rights', Report of the High Commissioner for Human Rights, Commission on Human Rights, (E/CN.4/2002/54: para. 37).

45 ILO/WTO, *op.cit.*

46 Bartels, L., 'Social Issues: Labour, Environment and Human Rights', in S. Lester and B. Mercurio (eds), *Bilateral and Regional Trade Agreements: Commentary, Analysis and Case Studies*, Cambridge University Press, Cambridge, 2008.

47 However, the human rights indicators relied upon, such as the Freedom House Index and Humana Rating, are themselves highly questionable, including for their failure to incorporate economic, social and cultural rights, calling into question, to a degree, his conclusions. Sykes, *op.cit.*, p. 73.

outset. First, more often than not, negative impacts are not the direct result of trade agreements, but trade agreements might be the trigger for changes which, in the absence of appropriate adjustment measures or in combination with other factors, lead to regressions in the enjoyment of rights. Second, trade agreements do include various safeguards and exceptions which, leaving aside the question of their effectiveness and coverage, potentially provide a means for States to avoid some negative impacts of trade agreements on human rights. With this in mind, four major concerns arise.

First, increased competition due to trade openness could threaten the livelihoods of those unable to compete on the international market. Increased competition can lead to both job creation and job destruction in the short and long term, the extent of which depends on a variety of country-specific factors such as the structure of industry and employment. However, even where increased competition has overall positive effects on employment and wages, average wage increases might hide wage changes that affect some workers negatively in the long-term.[48] In agriculture, increased market access has sometimes led to import surges and detrimental effects on competing domestic sectors, resulting in the marginalization of small farmers, increased rural unemployment and poverty as well as food insecurity, as local production turns towards export production and cheaper imports seriously erode agricultural sectors considered vital to food security.[49] This in turn can increase inequality in society, and, potentially, discrimination where ethnic minorities, women, persons with disabilities or others are affected disproportionately. These problems are exacerbated where trade agreements do not achieve balanced liberalization between developed and poorer countries.[50]

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48 ILO/WTO, *op.cit.*. See also Howse and Teitel who note that enhanced foreign competition due to trade liberalization can lead to job losses in the absence of appropriate adjustment measures. Howse, R., and R.G. Teitel, *Beyond the Divide: The Covenant on Economic, Social and Cultural Rights and the World Trade Organization*, Friedrich Ebert Stiftung, Dialogue on Globalization, Occasional Papers, No. 30, Geneva, April 2007, p. 14.

49 Breining-Kaufmann, C., 'The Right to Food and Trade in Agriculture' in Cottier, Pauwelyn and Bürgi, *op.cit.*, at p. 368, citing evidence from an FAO study of 14 countries: Food and Agriculture Organization, *Agriculture, Trade and Food Security: Issues and Options for the WTO Negotiations from the Perspective of Developing Countries*, Rome 1999. See also: See e.g., United Nations, 'Globalization and its Impact on the Full Enjoyment of Human Rights', Report of the High Commissioner for Human Rights, Commission on Human Rights, (E/CN.4/2002/54: para. 35).

50 For example, African countries have substantially liberated agricultural trade through trade agreements, such as the Cotonou Partnership Agreement, with the European Union. The European Union, on the other hand, has maintained its Common Agricultural Policy largely intact. Trade liberalization under the Cotonou trade regime, together with the heavy subsidies paid to EU farmers, has threatened the livelihoods of farmers in several African countries, since the local produce is more expensive and cannot compete with the cheaper imports from the European Union. The instability this can cause in food supply can affect the availability and accessibility of food through unsustainable food production patterns, with consequent negative impacts on the right to food. Nwobike, J.C., 'The Emerging Trade Regime Under the Cotonou Partnership Agreement: Its Human Rights Implications', *Journal of World Trade*, 40(2), 2006, 291-314, p. 303.

Second, trade agreements can, in some cases, lead to higher prices for essential goods and services and therefore reduce access to persons living in poverty. This concern arises principally in the area of intellectual property protection and its impact on the prices of pharmaceuticals, seeds and school books. For example, the impact of the TRIPS Agreement, and increasingly bilateral and regional trade agreements, on access to essential medicines has received considerable attention over recent years.[51] On the one hand, patent protection provides an incentive to invest in research and development of new drugs and trade mark protection guarantees a level of quality control for pharmaceuticals. At the same time, intellectual property protection can restrict access by increasing prices of patented and trade mark protected drugs and delay entry of cheaper generic drugs onto the market. While intellectual property protection is only one factor that can influence prices, it can at times have a critical impact. Where intellectual property protection increases the prices of essential medicines such as HIV treatments, blocking access for those who cannot pay, this can result in a negative impact on the right to health.

Third, trade agreements promote a market approach to the provision of goods and services which could lead to two-tier provision, favouring those who can pay and exacerbating inequality and discrimination. For example, there has been concern that the liberalization of trade in health services might lead to commercial approaches to health service provision, including the introduction of user fees, leading to a corporate sector focusing on the wealthy and healthy and an underfinanced sector focusing on the poor and sick. This in turn could lead to a brain drain of professionals towards higher paid positions in the private sector. Given that investment is generally motivated by commercial objectives, the promotion of investment through the liberalization of trade in health services is not necessarily the most appropriate way to ensure universal access to entitlements.[52] The causal chain between trade agreements and the move towards two-tier provision of services might prove difficult to demonstrate in practice given the many factors that can influence essential service provision.[53]

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51 See e.g.: Cullet, P., 'Human Rights and Intellectual Property Protection in the TRIPS Era', *Human Rights Quarterly*, 29, 2007, 403-430; Abbott, F.M., 'Toward a New Era of Objective Assessment in the Field of TRIPS *and* Variable Geometry for the Preservation of Multilateralism', *Journal of International Economic Law*, 8(1), 2005, 77-100; United Nations, 'The Impact of the Agreement on Trade-Related Intellectual Property Rights on Human Rights', Report of the High Commissioner for Human Rights, Sub-Commission on the Promotion and Protection of Human Rights, (E/CN.4/Sub.2/2001/13); Correa, C.M., 'Implications of Bilateral Free Trade Agreements on Access to Medicines', Public Health Reviews, *Bulletin of the World Health Organization*, 2006, 399-404; Chapman, A., 'The Human Rights Implications of Intellectual Property Protection', *Journal of International Economic Law*, 5(1), 2002, 861-882.

52 United Nations, 'Liberalization of Trade in Services and Human Rights', *op.cit.*, para. 44.

53 In particular, this raises the question of the extent to which trade agreements actually lead to privatization of services. For example, there is nothing in GATS which requires private sector service provision as such. Lang notes that trade agreements, such as GATS, can provide a vehicle through which to influence modes of thinking about trade and service provision which promote private sector provision and disparage public sector provision, even though, strictly speaking, they do not require private sector

Fourth, commentators have argued that trade agreements favour commercial or industrial trade interests and fail to deal with other aspects of trade affecting small farmers, migrant workers, indigenous peoples and others. For example, non-indigenous researchers have adapted indigenous peoples' knowledge in genetic resources into new innovations, or simply reproduced them in a more easily marketable or synthetic form, and protected them with patents, without the prior informed consent of the community or the equitable sharing of the arising benefits.[54] While trade agreements continue to strengthen intellectual property protection related to industrial products, discussions on the adequate protection of the cultural heritage and traditional knowledge of indigenous peoples have hardly progressed.[55] Similarly, while GATS promotes the liberalization of trade in services including through liberalizing the temporary movement of service suppliers, Howse and Tetel query whether the human rights of temporary service providers are always respected in the host country, suggesting that the reference to migrant workers as temporary 'service providers', rather than as individuals or persons, is an assumption that they are exempt from labour regulation, either in the host or home country or both.[56]

3.4 Trade agreements can limit government capacity to promote human rights

Governments, as the primary duty-bearers of human rights, must have the capacity – both in terms of legislative, as well as financial and technical, capacity – to take measures to promote and protect human rights. Yet trade agreements might impede governments from doing so. First, trade agreements might place greater strains on government financial capacity. For example, the lowering of tariffs takes away a source of government funding which could be devoted towards providing universal access to medicines, free primary and secondary education, housing schemes, protec-

participation in essential service provision. Lang, A.T.F., *Rethinking the Trade and Human Rights Debate: A Case Study of the General Agreement on Trade in Services and the Human Right to Water*, Phd Dissertation, on file with the author, see generally Chapter 3.

54 For example, patents have been granted over products derived from indigenous and local community knowledge such as: basmati rice (a product associated with South Asia); a process of extracting oil from the neem tree (used over generations in India); a process of healing a wound by administering turmeric (a culinary ingredient and traditional medicine used in India): Gonzales, A., and C. Monagle, 'Biodiversity & Intellectual Property Rights: Reviewing Intellectual Property Rights in Light of the Objectives of the Convention on Biological Diversity', Joint Discussion Paper, World Wildlife Fund, Center for International Environmental Law, 2001, Section I.

55 For example, the Fourth WTO Ministerial Meeting in Doha directed the TRIPS Council to examine the relationship between the TRIPS Agreement and the Convention on Biological Diversity and the protection of traditional knowledge and folklore. Yet, governments in neither the WTO nor the WIPO Inter-governmental Panel on Intellectual Property and Genetic Resources have been able to agree on a way forward. See: Ministerial Declaration of the Fourth WTO Ministerial Meeting in Doha, November 2001, (WT/MIN(01)/DEC/1), para. 19; International Centre for Trade and Sustainable Development, 'IGC Update', *Bridges*, 12(5), November 2008.

56 Howse and Tetel, *op.cit.*, p. 19.

tion of cultural heritage and social security schemes to compensate the 'losers' from trade liberalization. Moon, for example, notes how developing countries are concerned to maintain some flexibility to raise and lower tariffs in the area of agricultural trade, so as to maintain food security through agricultural production, even if that production might be inefficient. She also notes that, apart from protecting local production and rural livelihoods, tariffs are a valuable source of government revenue in developing countries and an entirely legitimate fiscal approach, particularly as large informal sectors can make the task of collecting income tax very difficult.[57] The problem is particularly acute in poorer African, Caribbean and Pacific (ACP) countries. Nwobike records that in Côte d'Ivoire, Sierra Leone and Uganda, trade taxes account for 40, 49 and 48 percent of government revenue respectively. He also notes studies suggesting that Economic Partnership Agreements between ACP countries and EU could result in Cape Verde and the Gambia losing 19.8 percent and 21.9 percent of their national incomes with Ghana and Senegal losing 10 and 11 percent respectively.[58]

Second, trade agreements could reduce the policy space available to States to take action to promote and protect human rights. Commentators have identified several examples as follows: rules on technical barriers to trade might restrict social 'fair-trade' labeling schemes as the label might discriminate against foreign goods or services not carrying the label;[59] government procurement rules might restrict governments' use of their purchasing power to promote social objectives, such as favouring domestic suppliers located in underprivileged areas, or run by indigenous or disadvantaged communities, on the basis that such preferential treatment might discriminate against foreign competitors;[60] rules on subsidies, quantitative restrictions and local content might prevent governments promoting local culture and protecting cultural diversity in film, television and radio;[61] national treatment rules applied to trade in services might prevent use of subsidies to domestic pro-poor service providers, or

57 Moon, G., 'The WTO-Minus Strategy: Development and Human Rights under WTO Law', *Human Rights and International Legal Discourse*, 2(1), 2008, 37-78, p. 65. See also: Trebilcock, M.J. and R. Howse, *The Regulation of International Trade*, Routledge, London and New York, Third Edition, 2005, p. 9.

58 Nwobike, *op.cit.*, p. 309.

59 Lopez, C., 'Social Labelling and WTO Law', *Journal of International Economic Law*, 5(3), 2002, 719-746; United Nations, 'Analytical Study of the High Commissioner for Human Rights on the fundamental principle of non-discrimination in the context of globalization', Report of the High Commissioner for Human Rights, Commission on Human Rights, (E/CN.4/2004/40: paras 43-50).

60 McCrudden, J.C. and Gross, S., 'WTO Government Procurement Rules and the Local Dynamics of Procurement Policies: A Malaysian Case Study' *European Journal of International Law*, 17(1), 2006, 151-185; C. McCrudden, 'Social Aspects of Sustainable Public Procurement: Some Preliminary Comments', Paper delivered at the Second Expert Meeting on Sustainable Public Procurement, Kifissia, Greece, 3-4 November 2003; United Nations, 'Analytical Study of the High Commissioner for Human Rights on the Fundamental Principle of Non-Discrimination in the Context of Globalization', Report of the High Commissioner for Human Rights, *op.cit.*, paras 28-34.

61 Hahn, M., 'A Clash of Cultures? The UNESCO *Diversity Convention* and International Trade Law', *Journal of International Economic Law*, 9(3), 2006, 515-552.

cross-subsidization schemes that favour people living in poverty or in underdeveloped areas where such schemes discriminate against or between foreign suppliers;[62] investment agreements might freeze social regulations and require compensation or exemption for foreign investors in the event of future regulations, even when those regulations apply equally to domestic and foreign companies alike.[63] While trade agreements include some safeguards and general exceptions, the question remains whether such provisions would protect all measures taken to promote social justice or protect against discrimination (in the human rights sense of the word) and whether trade agreements might have a chilling effect on government action to protect the poor and disadvantaged.

Third, trade agreements might stop governments retracting liberalization measures that have proven to work against human rights. Trade agreements have tended to be a one-way train to liberalization, permitting policy reverses in only very rare circumstances. GATS for example promotes the progressive liberalization of trade in services, the Agreement on Agriculture caps tariffs with a view to achieving further reductions, and the TRIPS Agreement sets minimum (but not maximum or even optimal) standards of intellectual property protection. Critics have tended to question whether this one-way approach is necessarily appropriate and have encouraged evidence-based approaches to trade reform that promote liberalization where it has a positive impact on human rights but changes direction where retrogressions in human rights result. Again, it is important to underline that trade agreements do include certain safeguards that allow temporary relief, for example, raising tariffs in the case of import surges or allowing withdrawal of liberalization commitments upon agreement of compensation to other affected States.[64] However, critics have argued that such measures are insufficiently comprehensive to deal with the problems arising from trade liberalization[65] and have suggested that the payment of compensation for with

62 For example, where one service provider provides a service to a wealthy area and one to a poorer area and the government requires 'cross-subsidization' (for example, a special tax on the supplier to the wealthier area) in favour of people in the poorer or disadvantaged area, the service provider to the wealthy area might claim it is suffering discrimination in relation to the service supplier in the poorer area. United Nations, 'Liberalization of Trade in Services and Human Rights', *Report of the High Commissioner for Human Rights*, Sub-Commission on the Promotion and Protection of Human Rights, (E/CN.4/Sub.2/2002/9: paras: 60-61).

63 United Nations, 'Protect, Respect and Remedy: A Framework for Business and Human Rights', Report of the Special Representative of the Secretary-General on the Issues of Human Rights and Transnational Corporations and Other Business Enterprises, Human Rights Council, (A/HRC/8/5: para. 35).

64 GATS, Article XXI, which includes the possibility of modifying or withdrawing commitments entered into a schedule although the modifying State must enter into negotiations on request from any other WTO Member affected by the modification with a view to reaching agreement on any necessary compensatory adjustment. GATT, Article XIX allows WTO Members to impose safeguards in the case of import surges on a temporary basis.

65 For example, Howse and Teitel argue that the WTO Appellate Body has defined the Article XIX safeguards narrowly requiring a strict demonstration that the events leading to the import surge could not reasonably have been foreseen. Howse and Teitel argue that 'Since it is hard through economic

drawal of liberalization measures could have a chilling effect on States' policy-making designed to protect human rights in the context of trade reform. Moreover, where flexibilities exist in WTO agreements that permit some room for governments to modify trade liberalization commitments, recent regional and bilateral trade agreements have tended to claw back those flexibilities.[66]

3.5 Trade agreements lead to a 'race-to-the-bottom' in human rights protection as countries try to compete on global markets

The argument that trade agreements might lead to a 'race-to-the-bottom' in human rights protection has generally focused on labour standards. Commentators have claimed that countries with low respect for labour standards have artificially low labour costs, thus attracting mobile capital. Trade liberalization could lead to production moving to countries with lower labour standards, placing pressure on developed as well as developing countries to decrease labour costs and harmonize labour standards down – a 'race-to-the-bottom'.[67] Developed countries have generally expressed fears of a 'race-to-the-bottom', given their higher labour standards in comparison to many developing countries. Developing countries on the other hand have perceived their cheaper labour costs as a comparative advantage in international trade and have expressed concerns that developed countries might seek to include provision of respect for labour standards in trade agreements as a means of protecting developed country production at their expense.

Empirical evidence as to the existence of a 'race-to-the-bottom' tends to be inconclusive although some recent studies suggest that violations of workers' rights in some developing countries have raised the volume of North-South trade.[68] Economic arguments tend to run in different directions. Granger et al note that decreased wages can promote competitiveness, while the use of child or forced labour leads to an increase in unskilled labour which can favour labour intensive production and

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methodology to identify a surge in imports as a factor separate from others affecting the fate of an industry, the consequence is that safeguard relief is very difficult to come by in the WTO': Howse and Teitel, *op.cit.*, p. 17.

66 See e.g. Abbott who notes how the US government has embarked on a process of negotiating TRIPS plus measures in bilateral and regional trade agreements that have the effect of limiting TRIPS flexibilities, potentially leading to higher drug prices and lower access: Abbott, F.M., 'Toward a New Era of Objective Assessment in the Field of TRIPS *and* Variable Geometry for the Preservation of Multilateralism', *op.cit.*, p. 90f.

67 Blackett, A., 'Wither Social Clause? Human Rights, Trade Theory and Treaty Interpretation', 31 *Columbia Human Rights Law Review*, 31(1), 1999-2000, 1-80, pp. 48f, 54.

68 For a review of empirical studies see: Granger, C., and J. Siroën, 'Core Labour Standards in Trade Agreements: From Multilateralism to Bilateralism', *Journal of World Trade*, 40(5), 2006, 813-836, pp. 820f. See also Blackett, *ibid*., p. 49 who notes that the race to the bottom is highly disputed from an empirical economic basis. Addo, K., 'The Correlation Between Labour Standards and International Trade: Which Way Forward? ', *Journal of World Trade*, 36(2), 2002, 285-303, p. 292 notes studies suggesting that core labour standards do not play a significant role in shaping trade performance.

exports.[69] On the other hand, the same authors note that violation of workers' rights impedes labour mobility and favours monopolistic behaviour of employers, which can reduce labour demand and work against trade. Ultimately, the authors argue in favour of some form of express linkage between trade agreements and protection of at least some labour standards as a means of promoting market efficiency.[70] Other studies suggest that high labour standards are conducive to high levels of productivity and ultimately a long-term comparative advantage,[71] that some labour standards may enhance market efficiency, and that other labour standards, such as the prohibition of child labour, raise a matter of principle that should override arguments based on economic costs and benefit.[72]

Much of the debate on the 'race-to-the-bottom' has focused on whether trade agreements should expressly include a social clause ensuring protection of workers' human rights in the context of trade reform. The debate has always been controversial, particularly for developing countries concerned to protect their perceived comparative advantage in low labour costs. In the WTO, the debate on a social clause has receded.[73] However, regional and bilateral trade agreements, such as NAFTA and the DR-US-CAFTA include specific references to labour standards, indicating that the debate outside the WTO is still alive.[74] Some commentators have argued that the WTO dispute settlement mechanism could employ customary rules of treaty interpretation to reconcile WTO agreements with internationally recognized labour standards in the event of a dispute arising in the area.[75] Other solutions to the problem lie in assisting

69 Granger et al, *ibid*., p. 819.

70 For example, non-discrimination in the work place avoids segmentation in the work place, prohibition of child labour allows competition between employers on a level field, and freedom of association and trade union rights balance employers' monopolistic power. Granger et al, *ibid.*, p. 821f.

71 Addo, K., *op.cit.*, p. 291 citing a study by Hepple: Hepple, B., 'New Approaches to International Labour Regulation', *Industrial Law Journal* 26(4), 1997, 353-366.

72 Brown, Deardorff and Stern, *op.cit.*, p. 18.

73 See e.g., The Singapore Ministerial Declaration of the First Ministerial Conference of the WTO, 13 December 1996, which appears to have silenced the discussion on trade and labour in the WTO. Paragraph 4 on 'Core Labour Standards' states that: 'We renew our commitment to the observance of internationally recognized core labour standards. The International Labour Organization (ILO) is the competent body to set and deal with these standards, and we affirm our support for its work in promoting them. We believe that economic growth and development fostered by increased trade and further trade liberalization contribute to the promotion of these standards. We reject the use of labour standards for protectionist purposes, and agree that the comparative advantage of countries, particularly low-wage developing countries, must in no way be put into question. In this regard, we note that the WTO and ILO Secretariats will continue their existing collaboration'.

74 NAFTA for example includes a Side Agreement requiring Parties to enforce their domestic labour laws, including in relation to occupational health and safety, child labour and the minimum wage and to continue to strive to improve standards. It also creates a Commission on Labor Cooperation including a Secretariat.

75 Blackett, *op.cit.*, pp. 79f.

developing countries, through trade, to enhance protection of labour standards and improve economic growth and development.[76]

3.6 Trade agreements limit the use of trade measures to improve the enjoyment of human rights abroad

States have at times relied on trade measures to react to human rights problems in other countries. Trade measures might take the form of 'trade incentives' to encourage good human rights practice abroad or 'trade restrictions' to punish human rights violators.[77] An example of the use of 'trade incentives' is the European Union's most recent preferential trading arrangements that condition preferential treatment on beneficiary countries ratifying and effectively implementing the core human rights conventions.[78] 'Trade restrictions', on the other hand, punish human rights violating States and take a variety of forms such as: a total ban on trade with a country as a general punishment, for example, in response to a UN or ILO resolution; a ban on certain goods or services connected with human rights abuse, such as a ban on goods produced with child or forced labour; or the imposition of an export ban to block the sale of goods or services that might lead to human rights violations. For example, the UN Special Rapporteur on the Question of Torture has recommended strict control on the export of materials specifically designed to inflict torture.[79]

The use of trade measures to change human rights situations abroad opens up a complex and difficult debate. The use of trade restrictions has been particularly controversial. With some notable exceptions such as Apartheid South Africa, the use of trade restrictions has not necessarily changed the patterns of abuse, has not tackled directly the underlying issues leading to abuse, such as poverty, underdevelopment and corruption, has not been successful in raising human rights standards across the board, and has tended to result in the punishment of the local population, rather than the élites perpetrating the abuse.[80]

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76 Addo, *op.cit.*, p. 299f.

77 The distinction between trade restrictions and trade incentives is drawn from Harrison, J., *The Human Rights Impact of the World Trade Oranganisation*, Hart Publishing, Oxford and Portland, Oregon, 2007, pp. 70f. See also: Denkers, J., *The World Trade Organization and Import Bans in Response to Violations of Fundamental Labour Rights*, Intersentia and School of Human Rights Research, School of Human Rights Series, No. 30, The Netherlands, 2008.

78 Harrison, *ibid.*, p. 118.

79 United Nations, 'Torture and Other Cruel, Inhuman or Degrading Treatment', Report of the Special Rapporteur on the Question of Torture, Theo van Boven, Commission on Human Rights, (E/CN.4/2005/62: para. 37).

80 In relation to trade sanctions applied to improve labour standards, Addo notes one study suggesting an even divide between success and failure among thirty cases where the EU threatened trade sanctions. Further, he refers to a survey of US economic sanctions over the 1970s and 1980s and noted positive outcomes in less than one case in five. Addo, *ibid*., pp. 298. See also Harrison, who combs through evidence of the usefulness of trade sanctions in promoting human rights and concludes that their utility is greatly disputed and there is a risk that trade measures are used by developed countries more for

Leaving aside the pros and cons of the use of trade to promote and protect human rights abroad, the question arises whether trade agreements obstruct such measures. As a general guide, rules on quantitative restrictions prevent bans such as trade sanctions on the import or export of goods. Similarly, most favoured nation treatment prevents discrimination against the goods of one importing country, such as a human rights violating country, in comparison to 'like' goods from another country. However, trade agreements, such as the WTO agreements, are not blind to these sorts of problems and several options exist which might save trade measures aimed at improving human rights abroad. The first option involves justifying the trade measure on the basis that the trade ban covers goods or services with are not 'like' other goods and services due to the connection with a human rights violation – in other words, soccer balls produced with child labour are 'unlike' soccer balls produced through adult labour.[81] The argument poses complicated legal issues and would not necessarily succeed, nor would it cover all trade incentives or restrictions.[82] The other options require the use of 'exceptions' to trade rules.

a) First, the Enabling Clause acts as an exception to MFN treatment which allows WTO Members to accord differential and more favourable treatment to developing countries without according the same treatment to other WTO Members.[83] The Enabling Clause could provide a means of justifying the use of trade measures as an incentive to improve human rights situations abroad, although its use is subject to certain provisos and its use to promote human rights has never been directly tested.[84]

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reasons of trade protectionism than really to improve the human rights situation abroad. In particular, Harrison observes that UN human rights mechanisms have widely recognized that the negative consequences of trade sanctions on human rights can potentially be significant. Harrison, *op.cit.*, pp. 69-81.

81 The test for 'likeness' depends on four criteria – the products end-uses in a given market; consumers' tastes and habits; the products properties, nature and quality; and, the products tariff classification. However, there is no single definition and determination is on a case-by-case basis. According to the Appellate Body, the fundamental determinative factor is the nature and extent of the competitive relationship between the two products being compared for 'likeness': *European Communities – Measures Affecting Asbestos and Asbestos Containing Products*, Report of the Appellate Body, March 2001, (WT/DS135/AB/R: paras 99, 101, 133).

82 For example, it would not save a total ban on goods irrespective of whether they are produced as a result of human rights abuse, as the human rights abuse would not be directly related to the banned goods or services.

83 See the 1979 Contracting Parties Decision on Differential and More Favourable Treatment, Reciprocity and Fuller Participation of Developing Countries (L/4903).

84 Namely: first, that the scheme is non-discriminatory in that it grants identical treatment to all similarly situated beneficiary countries; and, second, that the scheme must respond positively to the development, financial and trade needs of developing countries in order to justify the differential treatment. That need must be assessed according to an objective standard; the particular need must, by its nature, be such that it can be addressed through tariff preferences; the country providing the preferential treatment must ensure that the treatment does not impose unjustifiable burdens on other WTO

b) Second, where a country imposes trade sanctions in response to a UN Security Council resolution, the country could seek to justify the sanctions by relying on the security exceptions in Article XXI of GATT.[85]
c) Third, a country imposing trade restrictions could seek to justify the trade measure by reference to general exceptions to trade rules by arguing the measure was necessary to protect public morals, to protect human life or health or to prevent trade in products of prison labour – although the extent to which the general exceptions might include human rights concerns is highly debatable.[86]
d) A further exception exists in the form of a specific 'waiver'. A waiver allows a WTO Member to avoid an obligation under a WTO agreement with the consent of other WTO Members.[87]

The Waiver Concerning the Kimberley Process Certification Scheme for Rough Diamonds (the Kimberley Process) provides an example of this last exception. The Kimberley Process aims to control the trade in conflict diamonds through the introduction of a certification scheme that effectively makes a distinction between diamonds legally and illegally mined. In so doing, the Scheme seeks to restrict diamond trading contrary to WTO obligations concerning MFN treatment and the elimination of quantitative restrictions. The waiver ensures that WTO Members participating in the Scheme may benefit from the waiver of the strict application of these rules, allowing

members. *European Communities – Conditions for the Granting of Tariff Preferences to Developing Countries*, Report of the Appellate Body, April 2004, (WT/DS246/AB/R), paras 148, 163. See also: Harrison, *op.cit*., p. 116; Howse, R., 'Back to Court After *Shrimp/Turtle*?, *op.cit.*; Bartels, L., 'The WTO Legality of the EU's GSP+ Arrangement', *Journal of International Economic law*, 10(4), 2007, 869-886.

85 GATT, Article XXI, states that: 'nothing in this Agreement shall be construed … to prevent any contracting party from taking any action in pursuance of its obligations under the United Nations Charter for the maintenance of international peace and security'.

86 For a complete discussion on whether the terms 'public morals' and 'human life and health' can be considered as encompassing human rights norms according to customary rules of interpretation, see: United Nations, *Human Rights and the World Trade Agreements: Using General Exception Clauses to Protect Human Rights*, Office of the High Commissioner for Human Rights, New York and Geneva, 2005. Marceau notes that human rights treaties could be relevant to determining whether a measure was 'necessary to protect public morals as: first, as evidence of the importance of the values and common interests protected by the measure under examination; second, as evidence of the efficacy of the measures; and, third, as evidence of the good faith and consistent behaviour of the WTO Member defending the measure'. Marceau, G., 'WTO Dispute Settlement and Human Rights', *European Journal of International Law*, 13(4), 2002, 753-814, pp. 790f.

87 WTO Agreement, Article IX.3, sets out the procedures for the grant of a waiver noting that: '[i]n exceptional circumstances, the Ministerial Conference may decide to waive an obligation imposed on a Member by this Agreements or any of the Multilateral Trade Agreements, provided that any such decision shall be taken by three-fourths of the Members unless otherwise provided for in this paragraph'.

legal certainty for the scheme and protecting against future dispute settlement proceedings.[88]

While trade agreements appear to provide some means of saving trade measures designed to improve human rights abroad, there is no certainty of outcome and none of these approaches is watertight.

3.7 Trade law conflicts with human rights law

The seventh impact concerns the potential for provisions in trade agreements to conflict with human rights norms – a normative conflict. As previously noted, human rights treaties and trade agreements regulate overlapping subject matter, such as access to medicines, access to health services or the distribution of world food supplies, which raises the possibility of the two bodies of law regulating the same subject matter differently, and potentially leading to a legal dispute. Dispute settlement is equipped with formal, technical means to adjudicate between competing norms; however, it is not without its problems and a significant academic discussion has arisen around the potential and limits of dispute settlement as a means of resolving and avoiding conflicts between human rights law and trade law.[89]

A key issue in determining whether trade law conflicts with human rights law is the definition of 'conflict'. Two broad streams of thought have emerged on the definition of 'conflict' – one narrow, one broader. Jenks identified a narrow definition of conflict in his 1953 article 'The Conflict of Law-Making Treaties' where he concluded that a 'conflict of law-making treaties arises only where simultaneous compliance with the obligations of different instruments is impossible'.[90] In this way, Jenks considered

88 However, the Kimberley waiver has been criticized on several grounds: first, for not being necessary; second, for being only a temporary solution to a wider problem (waivers have to be renewed periodically); and, third, for potentially entrenching an exceptions approach that places trade norms as superior to human rights norms, requiring specific waivers to deal with potential conflicts when and if they arise. Schefer, K.N., 'Stopping Trade in Conflict Diamonds: Exploring the Trade and Human Rights Interface with the WTO Waiver for the Kimberley Process' in Cottier, Pauwelyn and Bürgi, *op.cit.*, p. 447.

89 See e.g., Marceau, 'WTO Dispute Settlement and Human Rights', *op.cit.*; Marceau, G., 'A Call for Coherence in International Law: Praises for the Prohibition Against "Clinical Isolation" in WTO Dispute Settlement', *Journal of World Trade* 33(5), 1999, 87-152; Pauwelyn, J., 'How to Win a World Trade Organization Dispute Based on Non-World Trade Organization Law?: Questions of Jurisdiction and Merits', *Journal of World Trade*, 37(6), 2003, 997-1030; Pauwelyn, J., 'The Role of Public International Law in the WTO: How Far Can We Go?', *The American Journal of International Law*, 95, 2001, 535-578; Pauwelyn, J., *Conflict of Norms in Public International Law: WTO Law Relates to Other Rules of International Law*, Cambridge University Press, Cambridge, 2003; Pauwelyn, J., 'Human Rights in WTO Dispute Settlement', in Cottier, Pauwelyn and Bürgi, *op.cit.*; Lopez, C., *The WTO Legal System and International Human Rights*, PhD Thesis, Graduate Institute of International Studies, Geneva 2005 (copy on file with the author); Bartels, L., 'Applicable Law in WTO Dispute Settlement Proceedings', *Journal of World Trade*, 35(3), 2001, 499-519; Trachtman, J., 'The Domain of WTO Dispute Resolution', *Harvard International Law Journal* 40, 1999, 333.

90 Jenks, C.W., 'The Conflict of Law-Making Treaties', *British Year Book of International Law*, 30, 1953, 401-453, p. 451.

conflict in terms of a collision of obligations whereby the two obligations could not be implemented together. Several other authors have adopted this narrow definition of conflict.[91] The narrow definition has the effect of restricting the likelihood of a tribunal finding a normative conflict. However, it fails to provide guidance on how to resolve problems in implementing treaty norms where, for example, two norms are inconsistent although not necessarily incompatible.

A broader definition of conflict goes beyond the situation of two opposing obligations to include 'inconsistent, incompatible and contradictory norms'. While the narrow definition launches a technical discussion on the definition of a conflict, the broader definition seeks solutions to implementation problems, shifting the focus from *how to define conflict* to *how to solve an alleged conflict*.[92] In its discussion of fragmentation of international law, the International Law Commission (ILC) appears to have followed similar reasoning. The ILC adopts what it refers to as a wide definition of conflict 'as a situation where two rules or principles suggest different ways of dealing with a problem'.[93] The ILC's reliance on a broader definition as the focus of its study necessarily covers situations beyond merely mutually exclusive obligations to include also situations where the goals of one treaty might frustrate the goals of another treaty without there being any strict collision of provisions.

In the context of discussion on the interplay between human rights norms and trade provisions, authors have taken different positions. Marceau, for example, cautions against a broad definition which would allow a third party – namely an adjudicator – to set aside obligations negotiated and agreed to by States. Instead, Marceau prefers the use of interpretation as a means to avoid conflicts.[94] On the other hand, Pauwelyn has favoured a broader definition and considered ways in which a human rights norm might be used as a defence to non-fulfilment of a provision of a trade agreement.[95] The debate on the issue is considerably more complex that suggested here – the point to be emphasized is the fact that disagreement exists on the definition, identification and response to normative conflicts between human rights norms and trade law.

Even relying on a broad definition of 'conflict', strict normative conflicts are unlikely - at least between UN human rights law and WTO law. For example, human

91 Pauwelyn, J., 'Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law', *op.cit.*, p. 167, citing other authors that have adopted a narrow definition of conflict covering only mutually exclusive obligations: Karl, W., 'Conflicts Between Treaties', in R. Bernhardt (ed.), *Encyclopedia of Public International Law*, North-Holland, Amsterdam, 1984, Vol. VII, p. 468; Klein, F., 'Vertragskonkurrenz', in K. Strupp and H.J. Schlochauer (eds), *Wörterbuch des Völkerrechts*, De Gruyter, Berlin, 1962, 555; Wilting, W., *Vertragskonkurrenz im Völkerrecht*, Heymanns, Cologne, 1996, p. 4.

92 Pauwelyn, *ibid.*, p. 169f.

93 United Nations, 'Fragmentation of International Law: Difficulties Arising From the Diversification and Expansion of International Law', Report of the Study Group of the International Law Commission, Finalized by Martti Koskenniemi, 2006, (A/CN.4/L.682: para. 25).

94 Marceau, 'WTO Dispute Settlement and Human Rights', *op.cit.*, p. 794.

95 Pauwelyn, 'Human Rights in WTO Dispute Settlement', *op.cit.*

rights conventions make rare reference to trade and when they do, the obligations on States parties are either vaguely worded, or worded in such a way as to make due reference to international law.[96] The obligation to provide patents over pharmaceuticals in the TRIPS Agreement, and the obligation to create 'the conditions which would assure to all medical service and medical attention in the event of sickness' and to take steps towards 'the prevention, treatment and control of epidemic, endemic, occupation and other diseases' in ICESCR, are hardly inconsistent, even if tensions might arise in their implementation – for example in the provision of essential medicines related to HIV treatments. The existence of exceptions and compulsory licensing provisions, and adoption of the Doha Declaration on Public Health and its reaffirmation of the right of WTO Members to protect public health, and the subsequent amendment of the TRIPS Agreement, appear to militate against any potential inconsistencies.[97] This is not to deny that implementation problems could arise; however, a strict normative comparison suggests that these human rights norms and trade provisions are at least not inconsistent, incompatible or contradictory. Nonetheless, with continued negotiation of new human rights treaties and the increased reach of bilateral and regional trade agreements beyond WTO law, there is a chance that an overlap leading to conflict could occur in the future.[98]

3.8 Enforcement of trade agreements is stronger than human rights enforcement which could lead to a prioritization of trade law over human rights law

The existence of strong mechanisms for the enforcement of trade agreements, such as the WTO's dispute settlement mechanism, has raised concerns that trade agreements might trump human rights, given the weaker enforcement mechanisms under human rights treaties.[99] Internationally, the WTO's dispute settlement mechanism includes the

96 For example, Article 11(2)(b) of ICESCR requires States parties 'taking into account the problems of food-importing and food-exporting countries, to ensure an equitable distribution of world food supplies in relation to need'. While this is a different approach to the regulation of agricultural trade than that adopted in the WTO's Agreement on Agriculture, its open wording offers many avenues for implementation which would not conflict with WTO obligations. Similarly, Article 30(3) of the Convention on the Rights of Persons with Disabilities sets out that: 'States Parties shall take all appropriate steps, in accordance with international law, to ensure that laws protecting intellectual property rights do not constitute an unreasonable or discriminatory barrier to access by persons with disabilities to cultural materials'. This provision identifies a clearer potential for conflict but appears to require any steps to implement the provision to be in accordance with international law, including WTO law.

97 The TRIPS Agreement, Articles 27(2) and 31(f), 'Amendment of the TRIPS Agreement', Decision of 6 December 2005, (WT/L/641).

98 For example, through a future negotiation of a protocol to the Convention Against Torture seeking a ban on trade in certain materials used for the purpose of torture.

99 Those human rights norms considered to be peremptory norms of international law would of course prevail. Consequently, a trade provision in conflict with the prohibition on torture, on slavery or on systematic forms of racial discrimination would be void – see Articles 53 and 64 of the Vienna

means to enforce judgments through the suspension of trade concessions in the case of non-compliance. In contrast, the various human rights treaty bodies have only quasi-judicial powers to provide views on disputes between rights-holders and States or between States, with no means of enforcing those views. Regionally, judicial mechanisms such as the European Court of Human Rights and the Inter-American Court of Human Rights exist although with very restricted means of enforcing economic, social and cultural rights, the rights most directly affected by trade agreements. Otherwise quasi-judicial mechanisms such as the European Committee on Social Rights also have authority to provide views on disputes between collectives of rights-holders and States although, as with the UN human rights system, with no power of enforcement. It is important not to over-exaggerate the impact of dispute settlement on human rights. Many factors beyond dispute settlement influence trade as well as human rights policy. Trade disputes arise on relatively few occasions, while other factors such as pressure from national groups, parliamentary debates, national-policy priorities and so on are constantly influencing both trade and human rights policy. In comparison, dispute settlement might have only a relatively limited influence.[100]

Nonetheless, commentators have expressed two principal concerns. First, the stronger trade dispute settlement mechanisms might ignore, misinterpret or give lower priority to human rights norms. The potential for dispute settlement mechanisms totally to ignore human rights obligations has diminished to an extent for a number of reasons. In the WTO context, the Appellate Body has established that the WTO agreements must not be interpreted in 'clinical isolation' from public international law, acknowledging that the WTO is not a hermetically closed regime.[101] There is a greater willingness, although not without controversy, both within the WTO and in investor-to-state disputes under regional and bilateral agreements, to receive *amicus briefs* from interested non-parties to a dispute, including from human rights organizations.[102]

Convention on the Law of Treaties. That leaves open the fate of other human rights norms affected by trade, such as the right to health, the right to food, workers' human rights for which there is no general hierarchy. Article 30 of the Vienna Convention applies an earlier treaty to the relations between the parties only to the extent that it is compatible with a later treaty. The maxim *lex specialis derogate legi generali* is a generally accepted technique of interpretation and conflict resolution in international law, it suggests that whenever two or more norms deal with the same subject matter, priority should be given to the norm that is more specific. See United Nations, 'Conclusions of the work of the Study Group on the Fragmentation of International Law: Difficulties arising from the Diversification and Expansion of International Law', International Law Commission, Geneva and New York, 2006, (A/61/10: para. 251), *Yearbook of the International Law Commission*, 2006, Vol. II, Part Two.

100 Abbot makes the point that the WTO Appellate Body is not involved in the daily implementation of the TRIPS Agreement and its influence is somewhat remote: Abbott, F.M., 'Toward a New Era of Objective Assessment in the Field of TRIPS', *op.cit.*, p. 84.

101 *United States – Standards for Reformulated and Conventional Gasoline*, Report of the Appellate Body, May 1996 (WT/DS2), p. 17. See also: Marceau, 'A Call for Coherence', *op.cit.*, p. 95.

102 In relation to the WTO, the Appellate Body accepts *amicus* briefs on a discretionary basis. See e.g. Howse, R., 'Membership has its Privileges: the WTO, Civil Society and the *Amicus* Brief Controversy', *European Law Journal*, 9(4), 2003, 496-510; Lim, C.L., 'The *Amicus* Brief Issue at the WTO', *Chinese*

However, it should be noted that dispute settlement tribunals outside the context of the WTO, such as the World Bank's International Centre for the Settlement of Investment Disputes, have not always been so open to human rights arguments. The Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations has observed that when investment cases go to international arbitration, they are generally treated as commercial disputes in which public interest concerns, including human rights, play little if any role.[103]

Where dispute settlement bodies do take human rights concerns into account, the question remains as to how they might be treated. Human rights arguments have to jump through a variety of technical hoops to make their case, such as whether human rights law could be part of the applicable law in a dispute, whether the particular trade-related human rights measure was 'necessary' for the protection of public morals or human life and health and so on. While this makes sense from a trade law perspective, the risk of the human rights issue losing out to trade provisions in the process is constantly present. Subjecting human rights measures to tests such as the 'necessity test' risks violating the normative underpinnings of human rights law which is based not on utilitarianism or efficiency – justifying a measure so that its impact on trade is the least possible – but on the protection of human dignity – justifiable in and on itself whether efficient or not.[104] Even where a trade dispute does consider human rights arguments, the question arises as to how specific rights might be referred to; for instance, to what extent would a dispute resolution mechanism take into account the general comments of the Committee on Economic, Social and Cultural Rights?

Second, the mere threat of stronger trade enforcement procedures might lead States to prioritize the implementation of trade agreements over human rights. This is often referred to as the chilling effect that trade agreements might have on protection of human rights in situations where implementation tensions arise. Harrison demonstrates this effect by reference to legislation proposed in Maryland that would have prohibited that US state from doing business with the military dictatorship of Nigeria or with firms operating in that country. The Clinton administration at the time lobbied heavily against the adoption of the Maryland legislation, it appears due to the fear that such

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Journal of International Law, 4(1), 2005, 85-120: In relation to investor-to-state disputes: *Biwater Gauff (Tanzania) Ltd v United Republic of Tanzania*, International Centre for Settlement of Investment Disputes, Procedural Order Number 5 allowing an *amicus brief* referring to the human right to water to be brought in the proceedings by: The Lawyers' Environmental Action Team, The Legal and Human Rights Centre, The Tanzanian Gender Networking Programme, the Center for International Environmental Law and the International Institute for Sustainable Development.

103 United Nations, 'Respect, Protect and Remedy: A Framework for Business and Human Rights', Report of the SRSG, *op.cit.*, (A/HRC/8/5: para. 37).

104 Garcia notes that in the contest between the trade efficiency model and the human dignity model of human rights law, when played out in the context of WTO dispute settlement, there is cause for concern that human rights will lose: Garcia, F.J., 'The Global Market and Human Rights: Trading Away the Human Rights Principle', *Brooklyn Journal of International Law* 25, 1999, 51-97, pp. 74, 82.

sanctions would be contrary to WTO rules.[105] Whatever the merits of using such measures to respond to human rights abuse, it does appear that the fear of the enforcement of WTO rules could affect their adoption in the future.[106]

Several approaches have been suggested to avoid these impacts. Suggestions have included the integration of human rights in trade agreements, for example, through the adoption of a social clause, a clear human rights exception to trade rules or a Ministerial Declaration on human rights and trade.[107] However, not only are these options politically difficult,[108] the value of shifting human rights concerns to the WTO or to other trade fora is questionable. Another proposal has encouraged the strengthening of human rights mechanisms, such as the ILO complaints mechanisms or the human rights treaty bodies, coupled with stronger cooperation between human rights and trade bodies.[109] Further, strengthening national human rights mechanisms could be particularly relevant given their proximity to the individuals concerned and their stronger influence nationally. In this regard, it will be interesting to examine the future impact that the recently adopted Optional Protocol to the International Covenant on Economic, Social and Cultural Rights has on strengthening legal protection of economic, social and cultural rights at the national level.

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105 Harrison, 'The Human Rights Impact of the World Trade Organization', *op.cit.*, p. 103.

106 *Ibid*., p. 104.

107 This proposition was made by the International Law Association (ILA) which would: pledge WTO Members to respect their existing universal human rights obligations; affirm support for the clarification by human rights bodies of the impact of human rights on trade rules and policies; acknowledge the need for harnessing trade and human rights to enhance welfare increasing cooperation among free citizens in trade; recognize customary rules of international treaty interpretation may require WTO bodies to take into account human rights in interpreting WTO rules; assert that WTO objectives, principles and exception clauses are flexible enough for consistent implementation of WTO and human rights norms; and, urge WTO dispute settlement bodies, if required by WTO Members, to take into account human rights as relevant legal context for the interpretation of WTO rules: International Law Association, Draft Seventh Report of the International Trade Law Committee, Toronto Conference (2006), paras 44-46.

108 The ILA admits this in making its proposition, *ibid.*, paras 44, 47-48.

109 Strengthening human rights bodies could include anything from strengthening the knowledge of experts on the impact of trade agreements on human rights, strengthening the functioning of such bodies such as mechanisms to follow-up on decisions and views adopted by expert mechanisms, improving secretariat services, and so on. Human rights political bodies, such as the Open-Ended Working Group on the Right to Development, and expert bodies, such as the Committee on Economic, Social and Cultural Rights (CESCR), have demonstrated some openness to consider how trade agreements affect human rights. See e.g. United Nations, 'Report of the High-Level Task Force on the Implementation of the Right to Development at its Second Meeting', Chairperson-Rapporteur, Stephen Marks, 2005 (E/CN.4/2005/WG.18/TF/3: paras 22, 59); CESCR held an informal consultation on the impact of international trade on economic, social and cultural rights in Geneva on 27-28 November 2006. For the first time, on 24 September 2008, the WTO Public Forum hosted a Panel organized by a human rights NGO, 3D Trade, Human Rights Equitable Economy, and the Office of the UN High Commissioner for Human Rights, on 'The 'New Geneva Consensus': Defining People Centred and Development-Oriented Trade Policy: Can a Human Rights Approach Help?' (see http://www.wto.org/english/forums_e/public_forum08_e/programme_e.htm – accessed 17 December 2008).

3.9 Trade agreements and trade institutions fail to respect the right to take part in the conduct of public affairs

Considerable criticism of the WTO, as well as of bilateral and some regional trade arrangements, has focused on their poor governance structures and the lack of civil society participation in trade fora. Issues of participation arise in a variety of areas, including: the lack of participation of individuals and their representative organizations in trade negotiations, both at the level of national policy-making and internationally; the lack of any civil society representation in international trade fora, such as the various trade committees of the WTO; and the low level of participation of civil society organizations in the monitoring and enforcement processes.[110] Generally speaking, a problem of representative democracy exists at the international level even beyond trade institutions. The United Nations Panel of Eminent Persons on the United Nations-Civil Society Relations concluded that even though more and more decisions that affect peoples' lives are being taken at the global level, representative democracy rests at the national and local level.[111] Trade fora, probably more than any other area of international relations, have attracted the starkest criticisms in this regard. However, Alvarez challenges the claim that issues of popular participation and WTO transparency raise human rights concerns and argues that human rights obligations are largely irrelevant in this regard. He observes that '[m]erely because the Appellate Body has dealt with the question of the admission of amicus briefs should not deceive us into thinking that questions of access generally are subject to judicial resolution based on blanket assertions that NGO participation is required as a matter of established human right'.[112]

What then are the obligations on States, nationally and internationally, to respect and ensure participation? The right to take part in the conduct of public affairs, freedom of expression and the right to seek, receive and impart information, freedom of association and assembly, freedom of movement and the right to a remedy are all relevant to ensuing popular participation in political and public processes. Of these rights, the right to take part in the conduct of public affairs and the right to seek, receive and impart information are particularly relevant in the context of trade. At the national level, the tendency of some governments to maintain secrecy and exclude

110 Howse and Matua have noted how trade institutions and processes such as those of the WTO have traditionally excluded non-governmental and inter-governmental organizations concerned with human rights, promulgating a deep-seated culture of secrecy and exclusion: Howse, R., and M. Mutua, *Protecting Human Rights in a Global Economy: Challenges for the World Trade Organization*, Rights and Democracy, Montreal, 2000. See also: United Nations, 'Analytical study of the High Commissioner for Human Rights on the Fundamental Principle of Participation in the Context of Globalization', *op.cit.*

111 United Nations, 'We the Peoples: Civil Society, the United Nations and Global Governance', Report of the Panel of Eminent Persons on United Nations-Civil Society Relations, (A/58/817 and Corr.1).

112 Alvarez, J.E., 'How *Not* to Link: Institutional Conundrums of an Expanded Trade Regime', *Widener Law Symposium Journal*, 7, 2001, 1-27, p. 8.

representative civil society organizations from trade policy formulation raises questions of participation and freedom of information. The extent to which individuals and their representative organizations have any right to participate in international fora is more ambiguous. However, the Human Rights Committee considers that the right to take part in the conduct of public affairs covers 'all aspects of public administration, and the formulation and implementation of policy at the international, national, regional and local levels'.[113] The unprecedented levels of participation (and impact) of persons with disabilities and their representative organizations during the negotiations of the Convention on the Rights of Persons with Disabilities has set a benchmark for participation at the international level. The increasing levels of participation in UN fora pose a direct challenge to the low levels of civil society participation in trade institutions.

3.10 Trade 'values' threaten human rights 'values'

At its simplest, this impact is based on a view that trade agreements embody an Efficiency Model, characterized by the promotion of economic growth and the augmentation of aggregate welfare, efficient production through the implementation of the theory of comparative advantage, minimal government intervention in the market place, and maximum economic freedom.[114] In contrast, human rights law promotes a Human Rights Model that: places primary importance on human dignity, if necessary above efficiency concerns; promotes the rights of all individuals, including those living in vulnerable or disadvantaged situations; encourages a proactive State as a guarantor of public goods and services (obligations to respect, protect and fulfil human rights); and views development in comprehensive terms beyond mere income creation to include promotion of civil, cultural, economic, political and social rights. The argument runs that human rights treaties and trade agreements promote these contrasting Models; however, trade agreements, particularly as a result of their stronger enforceability, are threatening the Human Rights Model.

Commentators take differing positions on the extent to which these Models of development – the Efficiency Model and the Human Rights Model – are contrasting or conflicting. Certainly, markets are important to the Human Rights Model. For

113 United Nations, 'The Right to Participate in Public Affairs, Voting Rights and the Right of Equal Access to Public Service (article 25)', Human Rights Committee, General Comment No. 25, para. 5.

114 Jeffrey Dunoff has coined the term the 'Efficiency Model'. The trade Efficiency Model stresses economic efficient patterns of production and the improvement of aggregate welfare through reliance on market forces to optimize the distribution and value of resources. According to Dunoff, the Efficiency Model defines the problem as 'how to maximize aggregate economic welfare, and the 'solution' is to reduce or eliminate government regulations that interfere with voluntary, welfare-enhancing market exchanges'. Dunoff, J.L., 'The Death of the Trade Regime', *European Journal of International Law*, 10(4), 1999, 733-762, p. 737, cited in Moon, G., 'The WTO-Minus Strategy: Development and Human Rights Under WTO Law', *op.cit.*, p. 43. See also: Garcia, F.J., 'The Global Market and Human Rights: Trading Away the Human Rights Principle', *op.cit.*.

example, as noted above, commentators emphasize that economic growth is necessary to provide those available resources and markets are important to achieve this. As Sen has observed, '[i]t is hard to think that any process of substantial development can do without very extensive use of markets'.[115] Similarly, many of the commentators mentioned in previous sections rely on legal and policy arguments focusing on exceptions and safeguards in trade agreements to 'save' human rights from the more extreme manifestations of the Efficiency Model. Other commentators have moved towards a critical appraisal of trade agreements, illustrating how a purer form of the Efficiency Model is increasingly being applied in trade agreements, setting similar 'reciprocal' standards of trade liberalization for developing countries as for developed countries, narrowing the development strategies available to poorer countries and exacerbating poverty and inequality.[116] Yet others have been forthright in their assessment that the two Models are clearly incompatible, on the basis that the two have radically differing views of the role of the State and on the concept of the individual, society and the relationship between the two and that the Human Rights Model will necessarily lose out in any contest.[117]

Whatever the relationship between the Efficiency Model and the Human Rights Model might be, it is important to emphasize that trade theory is not static and should not automatically be equated with the Efficiency Model in its purest form. While the neo-liberal project exemplified by the 'Washington Consensus' has strongly influenced current trade thinking,[118] other theories have previously dominated, such as Keynesian economics which have emphasized a greater level of State intervention and which might be more conducive to the positive obligations on States to take proactive steps to fulfil human rights. Indeed, commentators tend to suggest that the 'Washington Consensus' has now been discredited and the Director-General of the WTO, Pacale

115 Sen, *op.cit.*, p. 7.

116 The policies of the Thatcher and Reagan administrations in the 1980's saw a rise of neo-liberalism and the development of the 'Washington Consensus' with its mantra of 'stabilize, privatize, liberalize' and a retreat of State intervention in the market place. This, Moon argues, had a strong influence on Uruguay Round of negotiations which led to the adoption of the WTO Agreement. Moon, *op.cit.*, pp. 46-66; Nwobike, *op.cit.*, pp. 303-311.

117 First, that the two models have radically different views of the individual. While human rights law has a more textured and substantive conception of the individual and society and the relationship between the two, neo-liberalism effectively promotes the individual above society and rejects notions of State responsibility towards the individual. To illustrate the point, O'Connell contrasts the view of denial of adequate medical care of a particular group as a structural denial of the right to health with a neo-liberal view that the same situation would demonstrate a failure by individuals to make provision for their own health needs. Second, human rights law requires by its nature a strong State to guarantee rights, whether civil and political or economic, social and cultural rights. In contrast, the neo-liberal conception of the minimal State devoid of social responsibilities tends to move in the direction of a weaker non-interventionist State reducing the States ability to comply with its positive human rights obligations. O'Connell, P., 'On Reconciling Irreconcilables: Neo-liberal Globalization and Human Rights' *Human Rights Law Review*, 7(3), 2007, 483-509. Garcia argues that in any contest between the Efficiency Model and human rights in dispute settlement, human rights will lose. Garcia, *op.cit.*, p. 74.

118 Moon, *op.cit.*, pp. 37-78, pp. 44, 51.

Lamy, has promoted a more human international trading system as an alternative, through his 'Geneva Consensus'.[119] This dynamic process of trade thinking leaves room for HRIAs to provide evidence to support other models to influence the negotiation and implementation of trade agreements that might be more conducive to the protection of the human rights of the poorest and most vulnerable in the context of trade openness.

4 A STEP-BY-STEP PROCESS

4.1 General process

There is no single one-size-fits-all methodology for undertaking impact assessments. Each methodology has to respond to the requirements of the assessment itself and methodologies should improve over time as each assessment process gains from the experience of previous assessments.[120] However, impact assessment methodologies tend to follow a similar pattern of steps, whether they are environmental, social or human rights impact assessment methodologies, and whether they assess the impact of programmes, projects or policies, including trade policies. It is important to note that terminology does differ between methodologies, and methodologies might use the same term to describe significantly different steps.[121] One term which needs clarification upfront is the expression '*ex ante*'. Some methodologies use this term to refer specifically to impact analysis undertaken during trade negotiations and prior to the adoption of an agreement. The focus of the assessment therefore is specifically to feed into the negotiation process.[122] The development of an *ex ante* HRIA methodology for analysis of trade agreements relies on a wider understanding of the term, to include not

119 According to the Director-General, the 'Geneva Consensus' would be: 'a new basis for the opening up of trade that takes into account the resultant cost of adjustment. Trade opening is necessary, but it is not sufficient in itself. It also implies assistance: to help the least-developed countries to build up their stocks and therefore adequate productive and logistical capacity; to increase their capacity to negotiate and to implement the commitments undertaken in the international trading system; and to deal with the imbalances created between winners and losers from trade opening – imbalances that are the more dangerous to the more fragile economies, societies or countries. Building the capacity they need to take advantage of open markets or helping developing countries to adjust is now part of our common global agenda': in 'Humanizing Globalization', speech of Pascal Lamy, Director-General of the WTO, San Diego de Chile, Chile, 30 January 2006 (available at: http://www.wto.org/english/news_e/sppl_e/sppl16_e.htm – accessed 14 January 2009).

120 European Commission, *Handbook for Trade Sustainability Impact Assessment*, European Commission, External Trade, 2006, p. 17; Department of Foreign Affairs and International Trade, *Handbook for Conducting Environmental Assessments of Trade Negotiations*, DFAIT, Canada, 2006, (available at: http://www.international.gc.ca/assets/trade-agreements-accords-commerciaux/pdfs/handbook-e.pdf – accessed 10 February 2009), p. 38.

121 Blobel, M., M. Knigge, and B. Görlach, *Report on Trade, Environment and Sustainability Impact Assessment*, Concerted Action on Trade and the Environment, July 2005, p. 7.

122 For example, the DFAIT methodology: DFAIT, *op.cit.*, pp. 1f.

only an assessment during the negotiation process, but also an assessment directly after adoption of the agreement but prior to implementation, with a view also of influencing the direction of the reform programme surrounding the trade agreement.

With this in mind, the following summarizes the steps, common to many methodologies, that this dissertation proposes as a step-by-step methodology for HRIAs of trade agreements.[123] The steps have been chosen as such because: first, they provide a logical sequence of steps that ensures adequate preparation, elaboration of the subject matter to be analyzed, analysis and evaluation; second, they ensure that less relevant aspects of trade agreements are set aside early on in the process enabling the assessment to focus on only those trade measures will a potentially significant impact on human rights; and, third, they respect human rights principles identified in Chapter I. These elements become clear in the discussion below.

1. *Preparation* – the preparation stage clarifies, to the extent possible, the context of the assessment, identifying the relevant legal, economic, environmental, social, and regulatory context of the country in the form of a baseline study, identifying people affected by and responsible for the policy or project, considering whether an assessment is necessary, setting out the objectives, scale and focus of the assessment, and identifying the skills, resources and time available to carry out the assessment.
2. *Screening* – this involves narrowing the range of trade measures subject to the assessment by identifying those trade measures more likely to have significant impacts on the enjoyment of human rights.
3. *Scoping* – this stage identifies the terms of reference of the assessment exercise, describing in detail the elements of the policy or project to be assessed, identifying the negotiation or implementation of future scenarios to be assessed, identifying likely future impacts, identifying the indicators of measurement and significance criteria, as well as the data sources relied upon and the various assessment tools to be employed, identifying the stakeholders to be consulted and how to ensure popular participation.
4. *Analysis* – this involves collecting and analyzing data to verify the impacts of the policy or project identified during the scoping stage, as well as their likelihood and significance. It requires the evaluation of the assessment results, by examining the extent to which various impacts might cancel each other out, or combine to pro-

123 Adapted from: Barrow, C.J., *Social Impact Assessment: An Introduction*, Arnold, London and New York, 2000, p. 38; EC Handbook, *op.cit.*, pp. 17-19; Humanist Committee on Human Rights (HOM), *Health Rights of Women Assessment Instrument*, Humanistisch Overleg Mensenrechten, Utrecht, 2006; Hunt, P., and G. MacNaughton, *Impact Assessments, Poverty and Human Rights: A Case Study Using the Right to the Highest Attainable Standard of Health*, Submitted to UNESCO, 2006, pp. 35-45; the Interorganizational Committee on Principles and Guidelines for Social Impact Assessment, 'Principles and Guidelines for Social Impact Assessment in the USA', *Impact Assessment and Project Appraisal*, Vol. 21, Number 3, September 2003, 231-250, pp. 244-248; Blobel, *op.cit.*, p. 7.

duce cumulative effects, identifying which stakeholders are most implicated as a result, as well as any legal or policy ramifications flowing from the likely impacts.
5. *Recommendations* – considers what measures might optimize the likely positive impacts identified during the assessment stage, as well as measures to reduce or exclude negative impacts.
6. *Evaluation and monitoring* – the assessment should also undergo its own assessment, to consider the extent to which it has met its objectives and is acceptable to stakeholders and to identify lessons learned. This stage should establish, in consultation with stakeholders, a monitoring plan with a view to monitoring actual impacts once the policy or project has been implemented.
7. *Preparation of the report* – upon completion of the six substantive steps, a report must be compiled, setting out the impact assessment, recommendations on mitigation and enhancement measures, an evaluation of the process, as well as an outline for future monitoring.

Importantly, methodologies for *ex ante* impact assessments of trade agreements are generally iterative, beginning with a general or preliminary assessment which is deepened and narrowed at later stages to clarify specific impacts.[124] In this way, at least the first five steps are repeated at each stage as the assessment deepens and narrows. For example, the European Commission's methodology for *ex ante* Sustainable Impact Assessments of Trade Agreements (the TSIA methodology), when applied to the WTO Doha Round of trade negotiations, began with a preliminary assessment, then proceeded to more complex sectoral analyses based on the results of the preliminary assessment, which in turn combined to provide the basis for the final global report.[125] A methodology developed by the Canadian Department for Foreign Affairs and International Trade for *ex ante* environmental impact assessment of trade agreements (the DFAIT methodology) sets out a four stage analytical process which is applied to an initial assessment, a draft assessment, an assessment during the negotiations, and a final assessment.[126] The iterative process of assessment is an important means of dealing with the complexities inherent in the analysis of trade agreements given their wide sectoral, regulatory and geographical scope. By breaking down assessments into levels of assessment, a general impact assessment is given a higher degree of specificity through more detailed studies. At the same time, where a preliminary assessment reveals insignificant impacts then time and resources are saved by not having to undertak more thorough assessments. Given the complexity of trade agree-

124 Blobel, *ibid.*, p. 7.

125 George, C., and C. Kirkpatrick, *Sustainability Impact Assessment of World Trade Negotiations: Current Practice and Lessons for Further Development*, Working Paper Series, No.2, Impact Assessment Research Centre, Institute for Development Policy and Management, University of Manchester, 2003, pp. 6f.

126 DFAIT Handbook, *op.cit.*

ments and the differing levels of time and resources that will be available to undertake HRIAs, an *ex ante* HRIA methodology should also incorporate an iterative process.

The rest of this section describes each of the steps in the methodology and justifies why they are necessary for the specific context of *ex ante* HRIAs of trade agreements.

4.2 Step one: Preparation

The preparation stage is where the assessment is given context. It is at this stage that the terms of reference for the assessment are set composing elements such as: the purpose and focus; current levels of trade including areas of strength and problem sectors; the overall level of enjoyment of human rights; key stakeholders including rights-holders and government departments; as well as internal administrative arrangements such as budgets and human resources and internal procedures – particularly relevant where a government department or team in a large NGO takes the lead in undertaking an assessment and internal consultation is necessary.[127] The following elements are most appropriate for the preparation of an *ex ante* HRIA of a trade agreement.

Setting the purpose: An *ex ante* impact assessment of a trade agreement potentially could have many quite varied purposes, for example: exploring linkages between trade and human rights, informing policy-makers across government, developing policy packages and/or increasing transparency in decision-making.[128] Alternatively, the purpose might be more closely related to a particular negotiation process such as: in-depth analysis of likely impacts of a trade agreement on human rights; provision of information on the limits of negotiating positions and complementary policies; building an open process of consultation around negotiations; improvement of institutional and political dialogue on human rights with trading partners; setting a baseline for an *ex post* monitoring process once the trade agreement is adopted.[129] An additional purpose or aim might be to respond to requests from human rights bodies to undertake *ex ante* HRIAs of trade agreements with a view to ensuring synergies between human rights obligations and trade policy. Similarly, an HRIA presents an occasion not only

127 For example, the Integrated Impact Assessment methodology developed by the United Nations Environmental Programme (UNEP) identifies the purpose, focus, stakeholders, consultation process, data availability and the parameters of the assessment at this stage: United Nations, *Handbook on Integrated Assessment of Trade-Related Measures: The Agriculture Sector*, United Nations Environment Programme, Geneva, 2005, pp. 5-11; United Nations Environment Programme, *Reference Manual for the Integrated Assessment of Trade-Related Policies*, United Nations, New York and Geneva, 2001 p. 5-13. The methodology for *ex ante* environmental impact assessment of trade agreements developed by the Canadian Department of Foreign Affairs and International Trade includes a 'preparation' stage but focuses principally on establishing the internal administrative arrangements for conducting the assessment, reflecting its primary use as an internal bureaucratic aid, although it also establishes the scope or parameters of the assessment and notifies the public of the process: DFAIT Handbook, *op.cit.*, p. 45-47.

128 UNEP (2001), *ibid.*, p. 5.

129 EC Handbook, *op.cit.*, p. 12.

to assess impact of trade agreements on future enjoyment of human rights but also to identify existing stresses on human rights.

Setting the focus and parameters: An impact assessment might focus on a range of international trade agreements or measures. For example, it might examine free trade agreements, commodity agreements, preferential trade agreements or sectoral trade agreements, or a range of trade measures such as tariff measures, non-tariff measures, subsidies, investment measures or intellectual property protection.[130] Even if these are likely to be narrowed as the assessment proceeds, it is important to clarify the object of the assessment and its context at the outset. Similarly, it is important to clarify the assessments initial geographical scope, the sector or sectors to be examined, and time-frames for the assessment process.[131] An HRIA might choose to focus on one specific right at the outset, such as the right to health, in which case the planning stage should stipulate this clearly, bearing in mind the interdependence of rights and the possibility that the trade agreement might also affect related rights.[132] In addition, an HRIA requires a mapping of the human rights commitments undertaken by the Government regionally and internationally and the rights and obligations in those agreements that the trade agreement is likely to affect.[133]

Identifying stakeholders: It might be possible at the preparation stage already to identify key rights-holders affected by trade agreements, as well as government and non-government actors in situations of responsibility, although this exercise will reoccur at the 'scoping' stage. Stakeholders include people with direct and indirect dependence on the sector, those with authority to influence policy – representatives of ministries and parliamentarians – as well as individuals or groups with claims over agricultural resources – landowners, farmers, community groups including women, the poor, affected communities and indigenous peoples. Other stakeholders include NGOs and industry representatives, labour groups, consumer groups and intergovernmental organizations.[134] An HRIA could also set out the rights as well as the corresponding responsibilities on States and non-State actors at this stage. This can be important in the context of an HRIA as an *ex ante* HRIA of a trade agreement politicizes actors, making government, negotiators or corporations active partners in promoting human rights rather than recipients or beneficiaries of an impact analysis. For example, in relation to non-State actors, the International Federation for Human Rights (FIDH) has criticized the European Union's Trade and Sustainability Impact Assessment methodology for its focus on macroeconomic analysis and the failure to take into account the

130 UNEP (2001), *op.cit.*, pp. 9f.

131 *Ibid.*, pp. 12f.

132 For example, Hunt and MacNaughton as well as the HeRWAI methodologies focus specifically on right to health impact assessments of policies. Hunt and MacNaughton, *op.cit.*; Humanist Committee on Human Rights, *op.cit.*.

133 See e.g., Hunt and MacNaughton, *ibid.*, p. 36.

134 UNEP (2005), *op.cit.*, pp. 8f.

impact of the presence of transnational corporations.[135] Apart from identifying rights-holders and duty-bearers, it is important to identify relevant human rights actors, such as the national human rights institution, who might become partners in the exercise, or alternatively, potential actors in the follow-up to the assessment.

Determining the administrative framework: The relevance of this element of the preparation stage depends on the structure of the organization undertaking the impact assessment. Where governments, intergovernmental or large non-governmental organizations have principal responsibility for the assessment, it is important to propose mechanisms for coordination. The methodology for *ex ante* environmental impact assessment developed by the Canadian Department for Foreign Affairs and International Trade focuses most of the preparation stage on establishing an Environmental Assessment Committee consisting of various government departments to ensure consultation. The Committee has a pivotal role in defining the scope and in undertaking the assessment. For example, where the assessment is broad, the Committee might establish specialized working groups to focus on particular issues.[136] The European Commission's TSIA methodology also envisages the establishment of a steering committee for each assessment, consisting of trade negotiators from different sectors as well as representatives of departments concerned with the environment, social issues and international development. As the TSIA methodology relies on external independent consultants to undertake the assessment, the role of the steering committee focuses on defining specific issues that should be subject to assessment as well as helping to coordinate the formulation of policy for the different issues within the Commission.[137] For an HRIA, consideration might be given to expanding the administrative framework created to oversee the process so as to include the national human rights institution, as well as the government department with responsibility for human rights, and also potentially civil society representation.

Preparation of a baseline study: A key step in preparing for an HRIA is the preparation of a baseline study or assessment of the current enjoyment of human rights in the country. Impact assessment methodologies not relying on a human rights framework also rely on a baseline scenario – corresponding more or less to the present economic, environmental or social situation – which is generally treated as a neutral point of comparison.[138] An HRIA places an important emphasis on clarifying the

135 International Federation for Human Rights (FIDH), *Human Rights Impact Assessments of Trade and Investment Agreements concluded by the European Union*, Position Paper, February 2008 (available at: http://www.fidh.org – accessed 17 January 2009), p. 12.

136 DFAIT, *op.cit.*, p. 46.

137 Kirkpatrick, C. and C. George, 'Methodological Issues in the Impact Assessment of Trade Policies: Experience from the European Commission's Sustainability Impact Assessment (SIA) Programme', *Impact Assessment and Project Appraisal*, 24(4), December 2006, 225-334, p. 332.

138 For example, for the Initial Assessment, the DFAIT methodology poses a series of questions to identify the various effects of introducing a new trade measure by reference to 'the environment' or 'water/air quality', 'soil', 'flora and fauna', 'increase or decrease in production' and so on without explicitly analyzing the current status of the environment, water/air quality, levels of production, and so on:

baseline situation, not as a neutral means of comparison, but as itself a part of the assessment process. Reliance on minimum standards in human rights treaties as the framework of analysis naturally leads to an assessment of the current human rights situation against those minimum standards. The baseline therefore becomes part of the assessment which itself might be an undesirable rather than neutral situation which could improve or deteriorate as a result of the introduction of trade agreements. This in turn affects the rest of the assessment, requiring mitigation and enhancement measures, not only in relation to the trade agreement, but also to cope with existing stresses on human rights.

4.3 Step two: Screening

The next step in the assessment process is the 'screening' stage. Trade agreements are highly complex and dense documents covering a range of sectors and trade measures. For an assessment to be meaningful, it is important that it focus on only those trade measures that are likely to have significant impacts. This requires a limited review of secondary materials and expert judgment to identify the main causal links between a trade measure and the subject theme of the assessment (economy, social development, environment) and assess the significance of any resulting impact using a limited number of significance criteria.[139] Chapter II, section 2 provides an initial outline of those trade agreements, sectors and measures most likely to affect human rights as well as the human rights most likely to be affected, which should help in identifying those sectors, measures and rights to be subject of an impact assessment. However, it is important not to rely on that analysis as a blueprint. Each agreement is different, just as the trade and human rights situation changes between countries, thus the screening stage should consider trade agreements on a case-by-case basis.

Methodologies, with the exception of the TSIA methodology, tend to combine the 'screening' stage with the 'scoping' stage. However, there is a practical distinction between, on the one hand, screening-out unnecessary trade measures and, on the other hand, clarifying the scope of those measures subject to subsequent assessment. While the former narrows the provisions to be assessed, the latter expands upon the remaining provisions and clarifies their content. Consequently, it is proposed to maintain the distinction in developing an *ex ante* HRIA methodology.

DFAIT, *op.cit.*. The TSIA methodology proposes that the preliminary assessment include an analysis of the underlying environmental, social and economic stresses so as to identify areas of stress or potential stress due to changes in trade policy although more as a means of understanding additional factors which could magnify or diminish impacts due to the introduction of a new trade policy rather than as a means of assessing existing environmental or social standards: EC Handbook, *op.cit.*, p. 17.

139 Kirkpatrick, C., and N. Lee, *Further Development of the Methodology for a Sustainability Impact Assessment of Proposed WTO Negotiations*, Final Report to the European Commission, Institute for Development Policy and Management, University of Manchester, April 2002, p. 11f.

Four factors assist in determining the significance of impact as follows:[140]

- The extent of existing human rights stresses in the affected areas;
- The direction of changes compared to baseline conditions (positive or negative);
- The nature, magnitude, geographic extent, duration and reversibility of changes, including the likelihood of impacts having a cumulative effect;
- The regulatory and institutional capacity to implement mitigation and enhancement measures.

These four factors have been chosen as they provide a multi-dimensional indication of the potential impact of the trade measure – the breadth and the depth of the likely impact, a description of the nature of the impact, as well as an indication of the institutional capacity that could help respond to and avoid negative impacts. These elements together provide the basis to identify the possible significance of the impact and possible institutional responses and whether particular trade measures warrant further assessment.

In order to assist in the identification of the significance, a quantitative measurement can be helpful. Thus, the direction and significance of each impact can be indicated using a five-point scale – from -2, -1, 0, +1, +2, as well as a short qualitative description of the impact.[141] The results should be compiled in a table. However, scoring systems also carry risks and should be accompanied by a qualitative assessment. For example, civil society organizations have raised the risk that the scoring system employed by the European Commission in its TSIA methodology could result in the use of positive scores to 'trade-off' negative scores suggesting a net zero impact from a trade agreement, while the result could be quite different.[142] This could be particularly problematic for a human rights analysis of a trade agreement where losses amounting to abuse of human rights are accepted or 'traded-off' in light of gains in another area. This could lead to discrimination and increased inequalities, an outcome which an HRIA methodology should specifically avoid.

4.4 Step three: Scoping

With the exclusion of trade measures unlikely to have significant impacts, the assessment moves on to the 'scoping' stage which builds on many of the issues identified in the preparation stage with a view to setting the terms of reference for the rest of the assessment. While the 'screening' stage is a narrowing exercise, the 'scoping' stage is an elaboration of what has to be done for the rest of the assessment. The 'scoping' stage should identify or describe at least the following: the trade measure under

140 Adapted from: EC Handbook, *op.cit.*, p. 17; George and Kirkpatrick, 'Sustainability Impact Assessment of World Trade Negotiations', *op.cit.*, p. 9.

141 Kirkpatrick and Lee, *op.cit.*, p. 22.

142 Blobel, *op.cit.*, p. 9.

assessment and a range of potential negotiation scenarios; the geographical context and time horizons; an initial indication of the likely impacts according to the ten impact categories identified in Chapter II, section 3; assessment priorities based on those likely impacts; indicators of impact and impact significance criteria; data collection and analysis techniques; and, a detailed consultation and participation plan.[143]

The *identification of trade measures and negotiation scenarios* is an important yet complex step in the 'scoping' stage. First, each trade measure should be described – a tariff, subsidy, investment measure, intellectual property rule and so on - and the specific component of the measure to be assessed should be specified – tariff level, extension of patent protection by five years, granting of national treatment and market access for a specific service sector etc. Once the trade measure has been clarified, negotiation scenarios are developed. Where the *ex ante* assessment takes place before or during trade negotiations, the final terms of the agreement will not yet be clear so a range of negotiation scenarios should be identified – for example, different levels of reduction in tariff levels. This step is complicated by the fact that States tend to protect the confidentiality of negotiating scenarios so as not to reveal their hands to their opponents through a public impact assessment process.[144] Consequently, negotiation scenarios must be created without necessarily having reference to real negotiation positions. In the event that an *ex ante* impact assessment occurs directly after negotiations but prior to implementation (as in the Costa Rica case study in Chapter III), the identification of negotiation scenarios is no longer relevant although the assessment could measure several potential implementation scenarios.

Where negotiation scenarios are relevant, the question then becomes what range of scenarios should be referred to. The initial implementation of the European Commission's TSIA methodology attempted to assess a selection of negotiation scenarios. However, this became too complex and instead the assessment examined an outer limit liberalization scenario in comparison to a baseline scenario (corresponding to either current trade policy or full implementation of existing trade agreements).[145] This simplified the assessment process by limiting the assessment to two outer limit scenarios, while still permitting assessment of the likely impact of intermediate negotiation positions by means of inference.[146]

One issue to examine in the scenario-building state is whether to assess the impact of increasing trade protection. Civil society organizations have criticized the TSIA methodology for not also assessing a 'de-liberalization' scenario that would consider the impact of raising new trade barriers, for example, to protect against or remedy

143 Adapted from Kirkpatrick and Lee, 'Final Report', *op.cit*., p. 12; EC Handbook, *op.cit.*, pp. 8, 17; UNEP (2001), *op.cit.*, pp. 12f.

144 Kirkpatrick and George, 'Methodological Issues', *op.cit.*, p. 331.

145 In many countries, current trade policy might not correspond to existing commitments to liberalize trade – for example, due to non-fulfilment of obligations or longer time frames for implementation in the case of developing countries which might not have expired.

146 Kirkpatrick and George, 'Methodological Issues', *ibid.*, p. 329.

negative environmental, human rights or social impacts.[147] The decision not to assess 'de-liberalization' scenarios in TSIAs has been justified on the basis that negotiations have not considered 'de-liberalization' and that TSIAs have not been devised with a view to assessing the desirability of liberalization.[148] In developing a methodology for *ex ante* HRIA of trade agreements, the possibility of including a 'de-liberalization' scenario should not be excluded so lightly. Where there is some likelihood that trade liberalization would lead to an abuse of human rights, an HRIA could potentially include a recommendation to reverse liberalization or include a new safeguard or trade restriction in the agreement. An HRIA should also assess this scenario in order to establish the most appropriate trade measure that is consistent with a State's human rights obligations.

The *indicators* to include should also be identified during the 'scoping' stage. The selection of indicators is important to provide meaning to what is being measured and should be tailored towards the trade measure under assessment and the subject of the assessment. Existing methodologies tend to emphasize the importance of having few but operational indicators that allow meaningful conclusions on the connection between changes in trade measures and impacts on the economy, society and the environment. The TSIA methodology relies on core indicators or themes, of which three are social themes, namely, equity and poverty, health and education, and gender inequalities.[149] Key indicators are chosen within those headings according to a set of criteria providing flexibility to adapt indicators to the specific sector and country under assessment.[150] Chapter II, section 5 below examines the specific requirements of human rights indicators of trade impacts in greater detail.

In addition, *significance criteria* should be identified in order to help prioritize the trade measures and their impact to be assessed. The DFAIT methodology mentioned above relies on a wide number of criteria, including nature of the impact (positive, negative, cumulative), duration, frequency, permanency, magnitude, impact on quality and quantity of environmental indicators, geographical cover, timing, effects on people resulting from environmental impacts, as well as the level of risk and uncertainty of the impact occurring.[151] An alternative is the use of a scoring system as identified in the 'screening' stage.

A further element of the 'scoping' stage is the *identification of likely impacts* that will have to be assessed. While trade agreements might have some direct impacts on the enjoyment of human rights, more often impacts are indirect and appear as flow-on effects from other impacts, such as economic impacts. It is helpful to set out the causal chain that illustrates first the initial economic impact of a proposed trade measure and then traces subsequent impacts on production systems, employment, prices and

147 Blobel, *op.cit.*, p. 8; Kirkpatrick and George, *ibid.*, p. 329.
148 Blobel, *ibid.*, p. 8; Kirkpatrick and George, *ibid.*, p. 329.
149 Kirkpatrick and Lee, 'Final Report', *op.cit.*, p. 22.
150 EC Handbook, *op.cit.*, p. 29.
151 DFAIT, *op.cit.*, p. 55.

government revenue, through to impacts on human rights.[152] Identifying the causal chain between a trade measure and its eventual impact, as well as identification of the likelihood and significance of that impact, relies on information drawn from existing studies, knowledge and expert judgment. This can be a complicated task given that the causal relationships between impacts and some aspects of the trade agenda – such as tariff changes – are relatively well understood, while for others there is a lack of information and knowledge.[153] The ten categories of impact set out in Chapter II, section 3 should provide a template for identification of impacts. It is also useful to include a temporal element in the identification of impacts, namely, by identifying longer-term dynamic effects with a view to understanding the longer term and cumulative gains and threats brought about through changes to trade agreements.[154] While long terms gains cannot justify a breach of human rights, they could help in the development of complementary measures or in identifying the likely gravity or extent of the breach. In addition, the 'likelihood' of impacts should be identified. Likelihood is a qualitative value which can be expressed in a simplified manner using a scale covering never, yearly, monthly, weekly, daily, continuously. Determination of 'likelihood' relies on a mixture of expert judgment and measurement through the use of existing knowledge and materials as well as past experience.[155] Upon identification of impacts, the *assessment priorities* can be indicated. This can help in the development of a work plan, ensuring that more serious impacts are assessed as a matter of priority, taking into account time and resource constraints.

The appropriate *assessment tools and techniques* for collecting and analyzing data should be identified with a view to verifying the identified impacts, their significance and likelihood. As with indicators, this issue is dealt with in greater detail in Chapter II, section 5 below. At this stage it is important to note that a mix of qualitative and quantitative techniques is most appropriate to the analysis of trade agreements.

A *consultation and participation plan* should be elaborated during the 'scoping' stage. As previously noted, participation and inclusion are key principles of HRIAs and the success of participation depends significantly on how the assessment incorporates participation into its methodology. They involve consideration of several factors including time and resource needs, information needs, scope of groups approached, a balance of types of organizations, a balance of different opinions and viewpoints and so on. Stakeholders include a range of actors including national and international NGOs, trade unions, religious groups, local communities, the media, corporations, business associations, academics, professional bodies, intergovernmental organizations, ministries, parliamentarians and others.[156] Participation and consultation can occur through several modalities including the use of electronic media, use of existing

152 EC Handbook, *op.cit.*, p. 35.
153 Kirpatrick and George, 'Methodological Issues', *op.cit.*, p. 328.
154 *Ibid.*, p. 331.
155 DFAIT, *op.cit.*, p. 43.
156 EC Handbook, *op.cit.*, p. 25; DFAIT, *op.cit.*, pp. 22-23; UNEP (2001), *op.cit*., p. 18.

stakeholder networks, holding public meetings and workshops and attending meetings organized by stakeholders, use of publications by civil society, establishment of advisory committees consisting of stakeholder representatives, and publishing feedback.[157] A clear participation and consultation, plan should take into account modalities for participation and consultation as well as time and resource costs such as translation, resource allocation and information accessibility, so as to avoid creating expectations which cannot be met at a later stage.[158]

A distinction should be drawn between participation and consultation. Consultation refers to the two-way sharing of information, important for transparency and awareness-raising. The IIA agricultural sector methodology identifies the need to clarify the information required so that stakeholders have access to as much documentation as possible in the early stages of the process. Information includes the terms of reference of the assessment, notice of consultations, minutes of meetings, comments received on the process, related studies and any other relevant information. While information sharing and consultation is important for reasons of transparency and awareness-raising, the principal frameworks for trade impact assessment emphasize the importance of moving beyond consultation in the narrow sense of the word with a view to engaging in dialogue with stakeholders.[159] Nonetheless, civil society groups have criticized the process of public participation and consultation in trade impact assessments for being selective in the choice of stakeholders, for failing to provide sufficient information and for not providing a mechanism to ensure that stakeholder comments are taken into account by negotiators.[160] An HRIA methodology should ensure that participation is sufficiently inclusive to the maximum extent possible given time and budget constraints and that the participation and consultation plan is publicly available and developed in a transparent manner.

The development of a meaningful and effective plan for participation is a difficult task, particularly where impact assessments are general in nature or at the global or regional level. In such cases, meaningful participation could in fact be limited.[161] In the US, public participation in assessments is a requirement although the requirement is also limited and participation should not be 'excessively burdensome' and should be 'responsive to the needs of expedited action and confidentiality'.[162] The issue of

157 Kirkpatrick and George, 'Methodological issues', *op.cit.*, p. 327; UNEP (2001), *ibid.*, pp. 18f; EC Handbook, *ibid.*, p. 26.

158 UNEP (2005), *op.cit.*, pp. 9f.

159 EC Handbook, *op.cit.*, pp. 24f; DFAIT Handbook, *op.cit.*, p. 22. The DFAIT Handbook understands 'consultation' to constitute and interactive exchange and dialogue and closer to the term 'public participation' as used here.

160 FIDH, *op.cit.*, p. 12.

161 Kirkpatrick and George, 'Methodological Issues', *ibid*., p. 327.

162 United States Trade Representative, *Guidelines for Implementation of Executive Order 13141*, United States Trade Representative and Council on Environmental Quality, 2000, Part VI, 'Public Participation' (available at: http://www.ustr.gov/assets/Trade_Sectors/Environment/Guidelines_for_Environmental_Reviews/asset_upload_file556_5734.pdf – accessed 10 February 2009).

confidentiality poses particular problems for effective and meaningful participation, given that negotiators are not willing to risk strategic advantages in the negotiation process which relies on restricted access to key policy information.[163] These are issues which an HRIA will have to take into account through its methodology, particularly given the emphasis placed on public participation and transparency.

4.5 Step four: Analysis

The 'analysis' stage refers to the verification of the various cause-effect channels linking trade measures with potential impacts that were identified during the 'scoping' stage. Effectively, this stage is putting into practice the terms of reference elaborated during the 'scoping' stage. It essentially involves four principal steps: first, the collection of data; two, analysis of data by reference to impact indicators to see whether the likely positive or negative impacts identified in the 'scoping' stage are verified; third, an evaluation of those results giving them context and meaning and their implications for the enjoyment of human rights and the State's human rights obligations; and fourth, the compilation of an initial report.

Depending on the depth of the impact analysis, this stage of the assessment can potentially be quite laborious. In particular, an *ex ante* HRIA of a trade agreement should promote participation through the involvement of stakeholders in the analysis of results. This is potentially time-consuming and resource intensive, raising questions of practicability in the context of *ex ante* impact assessments undertaken during rapidly moving trade negotiations. Even where the *ex ante* impact assessment occurs after adoption of the agreement but prior to implementation, time might still prove to be constrained as governments are under pressure to begin implementation shortly after ratification. Further, the analysis of qualitative data and its incorporation into the draft report can be extremely onerous, it might reveal high levels of uncertainty and data gaps and might require additional site visits and further data collection and analysis.[164] The identification of assessment priorities during the 'scoping' stage should help in balancing concerns for meeting time, budget and data constraints with fidelity to the human rights framework.

An HRIA methodology also requires analysis of the results of the impact assessment by reference to the human rights framework. For example, a decrease in access to affordable medicines as a result of a trade agreement has to be analyzed by reference to the rights and obligations in human rights treaties, as understood by the various human rights bodies. There should be an analysis of whether the decrease in access constitutes an abuse of the right to health, whether certain individuals or groups suffer disproportionately due to the decrease, and what the decrease means in terms of the obligations on States to protect against discrimination and to take steps towards the

163 Kirkpatrick and George, 'Methodological Issues', *op.cit.*, p. 331.
164 Rights and Democracy, *op.cit.*, p. 26.

progressive realization of the right to health. To assist in this process, Hunt and MacNaughton provide a checklist to assist in the analysis of right to health impacts of policies with prompting questions covering the availability, accessibility, acceptability of quality of health goods, facilities and services, as well as in relation to progressive realization, core obligations on States, equality and non-discrimination, participation, access to information and accountability.[165] This is discussed in greater detail in Chapter II, section 5 below.

4.6 Step five: Recommendations

The inclusion of recommendations is essential for an *ex ante* HRIA given that the results would normally feed into a negotiation or implementation process. Existing methodologies refer to recommendations in terms of 'mitigation and enhancement measures' or 'flanking measures' – in other words, measures to avoid or reduce negative impacts of trade agreements or to optimize positive impacts. The term is not appropriate to an HRIA as a potential violation of human rights is not mitigated but rather avoided in the first place. This might require rethinking the negotiation strategy rather than working around it as is suggested by the term 'mitigation'. Consequently, the term used is the more neutral 'recommendations'. They are normally addressed to the parties to the negotiations or agreement; however, they could also be directed to other actors such as international organizations, national human rights institutions or other human rights bodies, civil society groups or others. Recommendations might refer to:[166]

a) Measures built into the trade agreement itself such as a modification of a trade measure, the inclusion of a safeguard mechanism or exception, changes to the timing of implementation;
b) Measures included in a parallel agreement or side-letter to the agreement, such as interpretative statements or creation of institutional arrangements to help implement programmes of common interest to the parties to mitigate negative impacts or to monitor implementation of the agreement;
c) Technical cooperation or capacity-building projects to improve infrastructure, access international institutions and human rights bodies, improve data collection and analysis and so on;
d) National measures directed towards remedying market imperfections, such as pricing mechanisms, government support through subsidies, tax measures, micro-credit schemes and so on;

165 Hunt and MacNaughton, *op.cit.*, pp. 40, 41, 64, 65.
166 Kirkpatrick and Lee, 'Final Report', *op.cit.*, p. 14; UNEP (2001), *op.cit.*, pp. 45f; DFAIT, *op.cit.*, p. 56; UNEP (2005), *op.cit.*, p. 67.

e) Regulatory measures, including the adoption of human rights legislation or regulations, private sector regulation, ratification of international instruments, consumer protection legislation and so on;
f) Voluntary measures such as adoption of industry standards, codes of conduct, eco-labeling and fair trade schemes;
g) Institutional measures to enhance public participation, improve transparency around trade negotiation and implementation of agreements including access to information, and to strengthen accountability mechanisms;
h) Abandonment of the trade agreement, identification of 'no-go' areas or exclusion of certain trade measures.

The last option of abandoning an agreement or specific measure is included in only some existing methodologies, possibly due to the fact that methodologies are often based on an existing decision to proceed with negotiating an agreement.[167] An HRIA methodology should never rule out the possibility of abandonment, even if an extreme scenario, in case a negative impact amounts to an abuse of human rights and where alternative solutions to avoid the abuse are not obvious. Furthermore, an additional possibility of raising a barrier to trade might also be relevant in such cases and the methodology should include this within the scope of mitigation and enhancement measures. A human rights approach to trade asserts that trade liberalization is not an end in itself but rather a means to an end – one of the end goals is the promotion and protection of human rights.[168] Accordingly, one of the aims of an HRIA is to assess the desirability of liberalization which involves the possibility of changing the direction of trade liberalization in light of reliable predications of negative impacts on human rights.

An HRIA should also consider not only trade measures but also human rights measures that might affect the impact of trade agreements. Existing methodologies place a significant emphasis on identifying mitigation and enhancement measures with goverments in mind. An HRIA should also identify strategies relevant to strengthening the capacity of individuals and groups to claim their rights, including by raising awareness of human rights through human rights education and strengthening capacity to claim rights through the use of grievance mechanism such as courts, quasi-judicial tribunals and human rights institutions. In this regard, an HRIA might also examine how to strengthen relevant institutional arrangements, in particular the strengthening of accountability mechanisms that provide individuals and groups with remedies as a result of human rights abuses.

Ideally, recommendations should themselves be subject to impact assessment so as to evaluate their ability to meet their objectives and to determine which mitigation

167 The DFAIT methodology includes it alongside other mitigation measures while the IIA methodology, for example, includes it as an extreme case. DFAIT, *op.cit.*, p. 68; UNEP (2001), *op.cit.*, p. 46.
168 United Nations, 'Liberalization of Trade in Services and Human Rights', *op.cit.*, para. 7.

and enhancement measures to include in the report. The assessment of recommendations should take into account: their effectiveness in meeting their goal; their level of consistency with human rights obligations; their effectiveness in improving enjoyment of human rights; their consistency with other obligations on the government; their cost-effectiveness; and their feasibility, taking into account the political, institutional and other processes required to support implementation.[169]

As with other steps in the assessment methodology, the development and choice of recommendations should seek public involvement to the extent possible. Hunt and MacNaughton for example refer to this step as 'debate options' and propose that a draft report with recommendations be circulated to stakeholders. Where the right to health framework does not provide any clear answers to respond to impacts, then the government must turn to those people affected by the policy to receive comments and to hear their views on which trade-offs should be made, what mitigating measures are necessary and what compensation might be due.[170] However, including public participation at this stage of the process might also lead to delays, at times considerable delays, as well as additional expenses and, again, the imperative of public participation might have to be balanced with the exigencies of *ex ante* assessment time constraints.[171]

4.7 Step six: Monitoring and evaluation

Including a step on monitoring and evaluation provides a means of promoting some form of follow-up to the HRIA so that it does not become a one-off exercise. In this way, the results of an *ex ante* HRIA can become the baseline study for a later *ex post* HRIA. This could serve several functions including: first, an *ex post* impact assessment of the trade agreement on human rights after a period of implementation to examine the real impacts on human rights; second, an *ex post* impact assessment to examine the extent to which the trade agreement has been implemented; third, an *ex post* assessment of the findings of the *ex ante* impact assessment after a period of implementation to examine the accuracy of the initial assessment, including the effectiveness of any recommendations that were implemented; and, fourth, an evaluation of the *ex ante* impact assessment methodology in the form of a lessons learned exercise. Monitoring and evaluation helps not only strengthen the *ex ante* impact assessment methodology but also to follow implementation of the trade agreement so as to avoid any unsuspected negative impacts arising, to analyze new issues arising, to ensure targeted remedial action where necessary and generally to strengthen implementation.[172] The

169 Adapted from: Kirkpatrick and Lee, 'Final Report', *op.cit.*, p. 16; UNEP, (2001), *op.cit.*, p. 46.

170 Hunt and MacNaughton, *op.cit.*, p. 42.

171 Rights and Democracy reflect on the extent to which circulating draft reports for comment took much more time than anticipated and included additional expenses such as translating texts: Rights and Democracy, *op.cit.*, p. 27.

172 UNEP (2001), *op.cit.*, p.51. EC Handbook, *op.cit.*, p. 23.

strong emphasis placed on monitoring within human rights treaties highlights the importance of including monitoring and evaluation within an HRIA methodology. In particular, the results of *ex post* monitoring should feed into reports to human rights bodies.

A variety of institutions or organizations could have a role in undertaking an *ex post* impact assessment, such as an independent authority, a government department or the commissioning of an individual or an institution, such as an academic institution, to undertake the monitoring exercise. An obvious contender to undertake an *ex post* HRIA would be a national human rights institution. However, if a civil society or intergovernmental organization undertook the original *ex ante* HRIA, that organization might continue the process with *ex post* monitoring and evaluation. In addition, monitoring and evaluation should seek to involve relevant stakeholders, including those involved in the original assessment, and should be sufficiently independent to ensure objectivity and credibility.[173] Importantly, this can provide a means of continuing the process of mobilization and awareness-raising that the impact assessment should have launched, providing a strategy for further community involvement in trade policy-making and understanding of how to optimize benefits due to trade reform, and how to use grievance mechanisms effectively where negative impacts arise.[174]

4.8 Step seven: Preparation of the report

Finally, a report should be compiled including a description of the assessment process and the techniques employed, a description of the trade agreement, the assessment of the impact of the trade agreement on human rights and on government obligations, recommendations as well as any corrective action taken to respond to human rights abuses that came to light as a result of the assessment, a summary of any comments received on the impact assessment and/or recommendations, an evaluation of the process in the form of a lessons-learned chapter, as well as an outline of future monitoring processes and roles of relevant human rights actors. It is desirable to include in the report a process by which negotiators (in the case of trade negotiations) or government officials in relevant departments (in the case of an assessment targeted towards influencing implementation of an adopted trade agreement) should follow in considering how to incorporate the final report into the negotiation or implementation of the trade agreement.[175]

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173 Kirkpatrick and Lee, 'Final Report', *op.cit.*, p. 17; Hunt and MacNaughton, *op.cit.*, p. 45.

174 For the Rights and Democracy methodology, the development of recommendations itself generated expectations about continued monitoring of policies and involvement in the monitoring phase. Follow-up through developing monitoring plans can help to institutionalize these expectations. Rights and Democracy, *op.cit.*, p. 27.

175 The TSIA methodology has incorporated a process where an assessment indicates a 'red-light' – a conclusion of negative impact in one of the sustainability themes. This is a simple process which involves: first, indication of a 'red-light' in the conclusions of a report; second, an analysis by negotiators of the assessment; third, a conclusion about whether the analysis is 'robust'; fourth, in the

5 DATA COLLECTION AND ANALYSIS

5.1 Qualitative, quantitative and mixed-methods

Three broad approaches to the collection and analysis of data exist – quantitative, qualitative and mixed-methods. Quantitative research uses numbers and statistical methods and employs assessment techniques such as surveys and experiments. It tends to measure aspects of phenomena in numerical terms, and in doing so seeks general descriptions, or tests causal hypotheses in ways other researchers can replicate afterwards.[176] Qualitative research is descriptive rather than numerical or statistical and relies on open-ended data, often with the intention of developing themes from the data. It employs a wide-range of techniques such as open-ended interviewing, participatory case study techniques, participant observation, and review of documents and images, and focuses on an event or a unit as the basis of analysis.[177] As a systematized form of research, qualitative research is relatively new, with approaches becoming more visible only in the 1990s.[178] While at times, the two forms of research have been at loggerheads, qualitative research is increasingly accepted and qualitative and quantitative research techniques are sometimes combined in a mixed-methods approach.

This methodology proposes a mixed-methods approach for *ex ante* HRIAs of trade agreements. The justification for adopting a mixed-method approach draws first of all from the nature of the human rights framework, and second, from the specific requirements flowing from the need to analyze trade agreements and influence trade policy-making processes. These two factors are considered separately. First, as previously discussed in Chapter I, the four elements of the human rights framework are:

1. Human rights should be the explicit subject of a human rights impact assessment;
2. The process of the impact assessment should respect human rights;
3. The impact assessment should contribute to developing the capacities of 'duty-bearers' and 'rights-holders';
4. The impact assessment should involve human rights actors.

The second and third elements place a particular emphasis on the employment of qualitative approaches. For example, the objective of respecting human rights in the process of impact assessment highlights the importance of participation and ensuring

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case of a positive conclusion on robustness, the position must be redefined and where the conclusion is negative, maintenance of the negotiating position. George and Kirkpatrick, 'Sustainability Impact Assessment of World Trade Negotiations', *op.cit.*, p. 4.

176 King, G., Keohane, R.O. and S. Verba, *Designing Social Inquiry: Scientific Inference in Qualitative Research*, Princeton University Press, USA, 1994, p. 3; Creswell, J.W., *Research Design: Qualitative, Quantitative and Mixed Methods Approaches*, Sage Publications, California, USA, Second Edition, 2003, p. 18.

177 King, Keohane, and Verba, *ibid.*, p. 4; Creswell, *ibid.*, pp. 18f.

178 Creswell, *ibid*., p. 14.

multiple voices are heard in an assessment, favouring more subjective participatory techniques. Participatory techniques provide a means by which individuals and groups can influence and share control over development and policy initiatives and have a say in issues and decisions that affect them. In promoting participation in the collection and analysis of data, HRIAs can help to meet the requirement of respecting human rights in the assessment process. In a similar vein, the third element of the human rights framework – developing the capacity-building of 'duty-bearers' and 'rights-holders' – also tends to favour qualitative assessment techniques as they are better adapted to highlighting the real world experiences of individuals and communities, how this is or could be affected by trade reform, and what needs to be done to ensure beneficial human rights outcomes. It is difficult, and might be unhelpful, to reduce such experiences to a numerical or statistical value. Rather key-informant interviewing techniques of government officials or representatives of trading corporations and participatory in-depth interviewing techniques of 'rights-holders' that collect and analyze contextualized data would tend to be more appropriate to empowering individuals and building capacity of people and institutions in positions of responsibility.

At the same time, HRIAs must also adapt to the real world of trade negotiations and trade-policy formulation and this is where quantitative approaches are important. First, an HRIA of a trade agreement must provide information in a format that is potentially able to influence such processes, which, at least to some extent, means that an overly subjective approach that cannot be generalized in some way might fail to meet the mark. A quantitative approach helps to identify generalized and more objective conclusions of the cause-effect links between trade reform and human rights, necessary to promote an evidence-based approach to policy-making. Second, quantitative methods can be helpful in understanding the economic impacts of trade agreements, which is often the first step in understanding how trade agreements can ultimately affect people's lives and the capacity of government to meet its human rights obligations. For example, an economic impact on such things as prices and income must first be determined, before understanding the impact this might have on accessibility, availability, acceptability and quality of health care, education, water and so on. Consequently, a quantitative approach to HRIA appears to be at least as important as a qualitative approach.

Existing *ex ante* trade impact assessments tend to adopt a mixed-methods approach. The European Commission's Trade Sustainability Impact Assessments (TSIA) methodology identifies the usefulness of causal-chain analysis and economic modelling as means of providing clear and transparent hypotheses and key economic trends over such things as prices, welfare and income, particularly in relation to changes in levels of tariffs.[179] At the same time, the TSIA methodology recognizes the limits of quantitative assessment techniques, such as modelling, for being less effective in

179 European Commission, *Handbook for Trade Sustainability Impact Assessment*, European Commission, External Trade, 2006, p. 36.

relation to predicting the impact of new trade regulations, as appears in relation to intellectual property protection, investment rules and rules over trade in services.[180] Consequently, the EC methodology also relies on qualitative techniques such as expert opinion and case studies (potentially both qualitative as well as quantitative) as a means of providing focused and detailed results.[181] The methodology relies on expert opinion as a way to help with screening and scoping of trade measures, optimize the use of existing data and knowledge, and also fuse impact findings in quite different areas (economic, social and environmental) into a single report.[182] However, in spite of the fact that the TSIA methodology has emphasized the importance of mixing qualitative and quantitative techniques in theory, civil society organizations have criticized TSIAs for accepting economic modelling as *de facto* the best ways to explain the effects of trade, neglecting the potential for other disciplines, particularly social science techniques, to demonstrate impact. Civil society organizations have claimed that this has led to an economic bias in analysis, to the neglect of a holistic understanding of trade agreements.[183]

UNEP's Integrated Impact Assessment Reference Manual identifies a range of qualitative and quantitative assessment techniques. The Manual places economic modelling up front in its list of assessment techniques and refers to several general equilibrium models that have been developed to focus on natural and environmental sectors such as forestry, greenhouse gases and the agricultural sector.[184] The Manual also refers to a wide variety of qualitative techniques such as stakeholder analysis, consultative and participatory techniques, social surveys and interviewing.[185] In practice, the IIA studies have tended to mix qualitative and quantitative assessment techniques between studies, although modelling is prevalent in *ex ante* studies. Thus, for example, in the Phase II studies published in 2002, the China study, the only *ex ante* study in the series, relied on a quantitative partial equilibrium econometric analysis. The other studies of Argentina, Senegal, Ecuador, Tanzania and Nigeria relied on qualitative data assessment such as literature reviews and rapid participatory techniques, combined in the case of Argentina and Nigeria with cost-benefit

180 *Ibid.*, p. 36.

181 *Ibid.*, p. 35.

182 Kirkpatrick, C., and N. Lee, *Further Development of the Methodology for a Sustainability Impact Assessment of Proposed WTO Negotiations*, Final Report to the European Commission, Institute for Development Policy and Management, University of Manchester, 2002, pp. 37f.

183 'EU Trade and Sustainability Impact Assessments: A Critical View', Statement of European Civil Society Organizations, October 2006, pp.5f (available at: http://www.foeeurope.org/publications/2006/siastatement_eucivilsociety_oct2006.pdf – accessed 12 January 2009).

184 United Nations, *Reference Manual for the Integrated Assessment of Trade-Related Policies*, United Nations Environment Programme, New York and Geneva, 2001, pp. 29f.

185 UNEP (2001), *ibid.*, pp. 35ff.

analysis.[186] A general rule for *ex ante* HRIAs of trade agreements therefore is that they adopt a mixed-methods approach.

5.2 Human rights indicators

A conceptual and methodological framework

During the 'scoping' stage, the impact categories that are relevant to the assessment (chosen from the ten categories outlined previously) are identified. Logic and secondary materials should be used to illustrate the various cause-effect relationships between the introduction of a trade agreement and a human right. Once the right has been identified, it is necessary to choose appropriate human rights indicators that can demonstrate changes between the baseline and future enjoyment of a right after the introduction of a new trade measure. This requires establishing a limited number of valid and reliable indicators that can focus data collection and analysis while effectively demonstrating impact. This section adapts a conceptual and methodological framework and proposes criteria for selecting human rights indicators.

For present purposes, 'human rights indicators' are statements of qualitative and quantitative information that describe human rights or aspects of those rights in situations and contexts and measure changes or trends in the enjoyment of those rights over time.[187] This definition brings out three aspects of data requirements relevant to HRIAs of trade agreements: first, in keeping with the overall mixed-methods approach, the information should be both qualitative and quantitative; second, the requirement that the data describes human rights in situations or contexts is relevant to the need to collect data which describes the current or baseline enjoyment of human rights, an important step in the 'scoping' stage; third, the ability of the data to measure changes or trends in the enjoyment of rights relates to the need for indicators that can demonstrate future changes in the enjoyment of rights as a result of the introduction of a trade measure, an essential requirement of the 'analysis' stage of the methodology.

Reflecting the legal context of human rights which recognizes both rights of individuals and obligations on the State and others, an adequate description of human rights in situations and contexts requires not only a description of the enjoyment of a right by a 'right-holder' but also a description of the extent to which 'duty-bearers' are meeting their obligations to respect, protect and fulfil human rights. To facilitate the

186 United Nations, *Integrated Assessment of Trade Liberalization and Trade-Related Policies*, UNEP Country Projects – Round II, A Synthesis Report, (H. Abaza and V. Jha, eds), United Nations Environment Programme, New York and Geneva, 2002, pp. 8-17.

187 The definition is adapted from Andreassen and Sano who describe human rights indicators as 'quantitative or qualitative abstracts of information that can be used to describe human rights in situations and contexts and to measure changes or trends in the enjoyment of human rights over time'. Andreassen, B. and H.-O. Sano, *What's the Goal? What's the Purpose? Observations on Human Rights Impact Assessment*, Norwegian Centre for Human Rights, University of Oslo, Norway, February 2004, p. 15.

process of identifying human rights indicators that meet these imperatives, the Office of the High Commissioner for Human Rights (OHCHR), at the request of treaty bodies, has developed a conceptual and methodological framework with a view to providing a structured and consistent approach for translating human rights standards into indicators, relevant at the country level.[188]

At the conceptual level, the framework requires the indicator to be explicitly linked to the narrative of the legal standard of particular rights through the identification of 'attributes'. To do this, OHCHR has relied principally on the texts of human rights treaties. Consequently, the attributes of the right to health are: reproductive health; child mortality and health care; natural and occupational environment; prevention, treatment and control of diseases; and, accessibility of health facilities and essential medicines.[189] The attributes flow from Article 12(2) of the ICESCR. In order to permit greater precision, OHCHR divides stillbirth and infant mortality and child development into two attributes, one focusing on sexual and reproductive health, and the other on child mortality and health care. Similarly, the wording of Article 12(2)(d) is modified to a more precise formulation, allowing the identification of clearer indicators without, arguably, changing the sense of the treaty text. Where treaty texts have not provided clear attributes to specific rights, such as the right to food, OHCHR work has relied also on treaty body General Comments in the development of attributes.[190] The identification of 'attributes' therefore provides a conceptual link to human rights standards which ensures that the indicator is in fact an indicator of changes in human rights while at the same time focusing data collection on specific aspects of a right that are most relevant to the assessment. This conceptual step in the identification of indicators reflects that first element of the human rights framework underlying HRIAs, namely that 'human rights should be the explicit subject of the assessment'.

At the methodological level, OHCHR has identified three categories of human rights indicators which are calculated to measure both the extent to which 'duty-bearers' are meeting their obligations towards human rights as well as the extent to which 'rights-holders' are enjoying their rights. These three categories have been described as follows:[191]

188 See e.g., United Nations, 'Report on Indicators for Promoting and Monitoring the Implementation of Human Rights', Seventh Inter-Committee Meeting of the Human Rights Treaty Bodies and Twentieth Meeting of the Chairpersons of the Human Rights Treaty Bodies, Geneva, June 2008, (HRI/MC/2008/3). United Nations, 'Report on Indicators for Monitoring Compliance with International Human Rights Instruments', Eighteenth meeting of chairpersons of the human rights treaty bodies and fifth inter-committee meeting of the human rights treaty bodies, June 2006, (HRI/MC/2006/7).

189 See HRI/MC/2006/7, *op.cit*., Annex, Table 4.

190 See e.g., the right to food indicators in HRI/MC/2006/7, *op.cit.*, Annex, Table 3, that give the following attributes to the right to food: nutrition, food safety and consumer protection, food availability and food accessibility.

191 HRI/MC/2006/7, *op.cit.*, paras 17-19.

a) *Structural indicators* – these indicators reflect the human rights institutional framework that is necessary to facilitate the realization of the human right concerned and provide a measure of 'duty-bearers' *commitment* to human rights. Structural indicators identify: the recognition of specific rights through ratification of international instruments; recognition of rights in national laws; and the identification of institutional mechanisms for the promotion and protection of rights.
b) *Process indicators* – these indicators measure the *effort* undertaken by 'duty-bearers' to respect, protect and fulfil human rights through programmes, policies and other interventions. The respect for human rights in government processes has a significant bearing on the extent to which individuals do actually enjoy human rights.
c) *Outcome indicators* – these indicators capture attainments, individual and collective, that reflect the actual level of enjoyment of human rights – the *results* of the commitment and effort of 'duty-bearers' with regard to human rights. Thus, a process indicator might assess the existence and coverage of an immunization programme, while outcome indicators would capture life expectancy or mortality rates.

Accordingly, the structural, process and outcome indicators for each 'attribute' of the human right under consideration are identified. To do so, a table should be compiled which sets out the 'attribute' as well as the 'structural', 'process' and 'outcome' indicators. Table 9.1 of the OHCHR report provides an illustration of such a table in relation to the right to health. Where possible, the 'process' indicator should provide a link between the 'structural' and the 'outcome' indicator in order to understand as fully as possible the relationship between the acts and omissions of the State and the enjoyment of a right by an individual.

Table II.2 – Illustrative right to health indicators	
	Child mortality and health care (Article 12(2)(a) ICESCR)
Structural	Time frame and coverage of national policy on child health and nutrition
Process	Proportion of school children educated on health and nutrition issues
Outcome	Proportion of underweight children under 5 years of age

OHCHR has compiled tables of indicators for many of the rights in the International Bill of Human Rights and verified them through validation and feedback processes. The Office notes that the conceptual and methodological framework 'simplifies the selection of indicators, encourages the use of contextually relevant information, facilitates a more comprehensive coverage of the identified attributes of a right, and,

perhaps, also minimizes the overall number of indicators required to monitor the realization of the concerned human rights standards'.[192]

This conceptual and methodological framework for the present methodology is adopted. Conceptually, it focuses human rights indicators – and therefore data collection and analysis – on human rights norms and standards which is in keeping with the understanding of the term 'human rights' set out in Part One. Methodologically, it provides a means of complying with the terms of the human rights framework by helping to measure the willingness of 'duty-bearers' and the steps undertaken by them to meet their human rights responsibilities, as well as to measure the enjoyment of rights by individuals and groups. The inclusion of 'process' as well as 'outcome' indicators corresponds to the importance the human rights framework places not only on the extent to which rights are enjoyed as a result of trade reform, but also on whether the processes underlying trade reform respect human rights, for example, through being participatory and non-discriminatory. The addition of structural indicators to measure State commitment to human rights underlines one of the significant elements of the human rights framework, namely, the overt recognition of legal obligations on States and the need for institutional frameworks to support and promote respect for those obligations. While these indicators could be conflated into process indicators in some ways, the generally static nature of these indicators distinguishes these indicators from process indicators that are designed to capture momentary changes relevant to the achievement of human rights outcomes.

Further, the OHCHR framework compares favourably with indicator frameworks for existing methodologies for impact assessment of trade agreements. Of course, each methodology chooses an indicator framework to respond to the particular needs of the assessment. Thus, the UNEP IIA methodology discusses frameworks for environmental and social indicators which measure pressures from human activities on the environment, environmental change, and policy and household responses to environmental damage. This responds to the sustainable objectives of the IIA framework, but is not necessarily appropriate for HRIAs. While the UNEP frameworks seek to demonstrate the interaction between human activities and the environment, the HRIA framework seeks to describe the commitment and efforts of 'duty-bearers' and the enjoyment of rights by individuals.[193] In this sense, both indicator frameworks serve their own purposes and a comparison is not necessarily relevant.

However, to the extent that there is overlap, the OHCHR framework offers the potential to arrive at a fuller understanding of the impact of trade agreements on human rights and the factors that might mitigate or enhance that impact. For example, the sustainable development indicator framework identified by the European Commission's TSIA impact assessment methodology identifies both target indicators and

192 HRI/MC/2008/3, *op.cit.*, para. 17.

193 United Nations, *Handbook on Integrated Assessments of Trade-related Measures: the Agriculture Sector*, United Nations Environmental Programme, New York and Geneva, 2005, p. 29.

process indicators, emphasizing the importance of measuring not only the final impact of trade on sustainable development but also to measure the 'key procedures, processes and practices which are needed to progress towards the long-term goal of sustainable development'.[194] The TSIA methodology resembles the OHCHR methodology to the extent that both include 'process' and 'outcome' indicators. The addition of 'structural' indicators in the human rights framework can provide crucial information to give a broader understanding of how 'procedures, processes and practices' might or might not affect the target indicators. Taking the example of child mortality and health care in Table 9.1, the structural indicator of the time frame and coverage of a national policy on child health and nutrition could be vital information in identifying whether the process indicators of the proportion of school-going children educated on health and nutrition issues has an effect on the outcome indicator of the proportion of underweight children under 5 years of age. The TSIA indicator framework, in neglecting to consider the structural indicator, might not be able to make sense of the indicators to the extent possible using the OHCHR framework.

A further point of comparison in favour of the OHCHR methodology is its basis in international human rights norms and standards. The TSIA methodology identifies three main themes to assist in the development of social indicators, namely: 'poverty', 'health and education' and 'equity'.[195] The methodology then identifies a list of criteria to help in the selection of indicators for particular assessment exercises.[196] The risk from this approach is that each assessment could base the choice of indicators on quite different understandings of the three themes, particularly given the open nature of terms such as 'poverty', 'health and education' and 'equity'. In contrast, the basis of human rights indicators in the international treaties provides a more objective basis for identifying the 'attributes' of indicators, drawing on internationally recognized definitions of themes. While there is always an element of subjectivity in identifying 'attributes', and an ambiguity in the meaning of some terms in human rights treaties, reliance on the text of internationally accepted treaties and, as a secondary source, authoritative statements of treaty bodies that have gained wide acceptance, should ensure a level of objectivity in the selection of indicators and, importantly, greater consistency across different assessment exercises.

Criteria for choosing indicators

The identification of the attributes and the categories of indicators provides a conceptual framework for the choice of the indicators themselves. This process of selecting

194 Kirkpatrick, C., N. Lee, et al, 'Further Development of the Methodology for a Sustainability Impact Assessment of Proposed WTO Negotiations', Final Report to the European Commission, Institute of Development Policy and Management, University of Manchester, April 2002, p. 23.

195 European Commission, *Handbook for Trade Sustainability Impact Assessment*, European Commission, External Trade, March 2006, p. 28.

196 *Ibid.*, p. 29.

indicators must take into account the various data-related, conceptual and political challenges facing such an exercise. Barsh illustrates some of the problems associated with the construction of indicators, which, although unrelated to assessment of trade agreements, provide relevant lessons. One issue relates to the importance of precision. For example, relying on 'torture' or 'incidence of torture' as an indicator of 'state repression' is inexact as it is not possible to observe every gaol and police station in the country. The real description of the indicator is 'news reports of torture'. Barsh also refers to the problem of slippage where indicators measure more or less than what they set out to measure. He gives the examples of the use of arrest rates as an indicator of 'crime' (leaving out unreported crimes) or rejected housing applications as an indicator of 'discrimination' (including other grounds for rejecting housing applications').[197]

The identification of criteria for choosing indicators can help to minimize some of the inherent problems of measurement. The most commonly identified criteria for human rights indicators are reliability and validity; other criteria include relevance, objectivity, suitability to measurement over time, and amenability to disaggregation by sex, race, disability and so on.[198] Reliability and validity are sometimes connected too closely with quantitative research and have come under criticism from some qualitative researchers.[199] While this could be problematic in the present context given the mixed-methods approach of the HRIA methodology, other qualitative researchers have demonstrated that the criteria can be adapted to the requirements of qualitative research and so they are retained for present purposes.[200] Reliability and validity can be described as follows:

197 Barsh, R.L., 'Measuring Human Rights: Problems of Methodology and Purpose', *Human Rights Quarterly*, 15, 1993, 87-121, pp. 90f.

198 See e.g., United Nations, *Human Development Report 2000*, United Nations Development Programme, Geneva and New York, 2000, p. 90; Fasel, N., and R. Malhotra, *Quantitative Human Rights Indicators – A Survey of Major Initiatives*, Discussion Paper, March 2005, on file with the authors, para. 14; HRI/MC/2006/7, *op.cit.*, paras 26ff; Landman, T. and J. Häusermann, 'Map-Making and Analysis of the Main International Initiatives on Developing Indicators on Democracy and Good Governance', University of Essex, Final Report, 2003, para. 23 (available at: http://www.oecd.org/dataoecd/0/28/20755719.pdf – accessed 7 January 2008); Gurr, T.R., and B. Harff, 'The Rights of Collectivities: Principles and Procedures in Measuing the Human Rights Status of Communal and Political Groups', in T.B. Jabine and R.P. Claude (eds), *Human Rights and Statistics*, University of Pennsylvania Press, Philadelphia, 1992. pp. 180ff. The European Commission's TSIA methodology notes that indicators should be: coherent and consistent; relevant; sensitive to differing approaches to achieving sustainable development; comprehensive in covering the different pillars of social development; specific and reliable; credible and transparent; and, illustrate trends over time. European Commission, 'Handbook', *op.cit.*, pp. 29f.

199 Kvale, S., and S. Brinkmann, *Interviews: Learning the Craft of Qualitative Research Interviewing*, SAGE Publications, United States of America, 2009, pp. 244f.

200 *Ibid.*, p. 245.

a) *Reliability* – Reliability refers to 'the extent to which measurements are consistent when repeated by the same observer, or by different observers using the same instrument'.[201] For example, if a researcher asks a set of questions of someone and then repeats those questions to the person on another occasion, the data is reliable if the interviewee gives the same responses on both occasions. Reliability is important because it lessens the degree of subjectivity in measurement, making the measurement more stable and consistent. The use of established measures that have already been substantiated as reliable provides one means of ensuring the reliability of the indicator chosen.
b) *Validity* – Validity has been described as the extent to which a measurement 'measures exactly what it is supposed to measure, no more and no less'.[202] In other words, if the indicator reflects a truthful description of the situation, the indicator is valid. Linking the choice of indicators with concepts enunciated in treaties can strengthen the validity of the measure. For example, using infant mortality rates as a measure of the right to health might strengthen the validity of the indicator given the express reference to the reduction of infant mortality in Article 12(2)(a) of the Covenant. In qualitative research validity can be conceived in a broader sense as pertaining to 'the degree that a method investigates what it is intended to investigate, to 'the extent to which our observations indeed reflect the phenomena or variables of interest to us''.[203]

The other criteria are as follows:

c) *Relevance* – the indicator has to relate to the issue being assessed or monitored. In the context of human rights impact assessments of trade agreements, that means that the indicator must relate to the particular aspects of a trade agreement or trade negotiations under examination so that the indicator can provide the basis for appropriate human rights responses to trade policy-making.
d) *Objectivity* – indicators should be chosen according to a sound and transparent methodology. If indicators reflect only certain aspects of the human rights framework, or of the right itself, then the validity of the measure can be called into question. This can be the case when ideological assumptions underlie a measurement project and indicators are chosen to reflect and even confirm that ideology.
e) *Suitability to measurement over time* – the indicator should be able to be measured over time so that progress or regression in human rights enjoyment in comparison to a baseline measurement is possible.
f) *Amenability to disaggregation* – disaggregation is important for several reasons. First, to ensure that data represents differential achievements on different individu-

201 Barsh, *op.cit.*, p. 94.
202 *Ibid.*, p. 95.
203 Kvale, *op.cit.*, p. 246, citing Pervin, L.A., *Personality*, Wiley, New York, 1984, p. 48.

als and groups. Such disaggregation might not always be possible, or alternatively, disaggregation might be more difficult in relation to some areas – such as race or ethnicity – than it is for sex, particularly where the basis for disaggregation is sensitive. Second, disaggregation also relates to another facet of indicators, namely where the indicator is a score, the indicator should be amenable to disaggregation in order to explain the basis for the scoring method.

g) *Data availability* – where data are already available, substantiating an indicator is easier. This could be relevant if a choice has to be made between two indicators serving similar purposes where data is available for one but not the other. Where data are not available, the extent to which the indicator is key to the assessment has to be balanced with other considerations such as availability of time and resources.

Depending on the measurement being undertaken, data to substantiate human rights indicators might come from existing data sources or alternatively might have to be created. *Ex ante* human rights impact assessments of trade agreements generally have to be undertaken with relative speed so that they can influence negotiations in a timely manner which might favour relying on secondary sources. Socio-economic statistical data provides one source of aggregated data sets and indicators based on objective quantitative or qualitative information which could be relevant to HRIA indicators. Many sources of data exist in this category, from non-governmental organizations to inter-governmental organizations and national statistics commissions, although the principal sources are official or governmental sources. Although some of this data relate explicitly to human rights, such as data from UNESCO and the ILO or the World Bank's World Development Indicators which include data on equality, much of it, such as the UNDP Human Development Report indicators or the MDG indicators, are not expressed using human rights terms and so should be adapted to fit the indicator in question.[204] Reports of the UN treaty bodies or of the Human Rights Council's Universal Periodic Review might also provide relevant data.

However, the importance of involving 'rights-holders' and 'duty-bearers' in the actual assessment process means that original data might have to be created at some stages of an HRIA where feasible – indeed, reliance on secondary sources alone might not meet the requirements of the HRIA framework. Moreover, secondary sources will generally be incomplete given the specific nature of the economic and social data relevant to demonstrating impact of trade agreements on human rights. The next section identifies techniques for collecting and analyzing data relevant to HRIAs of trade agreements.

204 Fasel, and Malhotra, *op.cit.*, para. 2.

5.3 Techniques for collecting and analyzing data

Five techniques

Economic and social science analyses have developed a broad range of quantitative and qualitative techniques that could be useful in collecting and analyzing data to demonstrate the likely impact of the trade agreement along the causal chain to the human right under examination. Five impact assessment techniques are presented here, which together provide the basic tools to predict and analyze both economic and human rights impacts, to promote participation and consultation with stakeholders during an assessment, and also to allow different depths of impact analysis given that each HRIA is faced with different time-scales and variety of human and financial resources. The rest of this section provides a brief introduction to each assessment technique and then identifies their relevance to collecting and analyzing data for HRIAs. The list provides a range of assessment techniques but should not be considered exhaustive. Data collection and analysis techniques should be adopted in light of the objectives of specific HRIAs. The five techniques are identified below.

First *economic modelling* provides a means of analyzing data using mathematical equations designed on the basis of trade theory to predict the future economic impacts of trade reforms, such as impacts on income levels and prices. Modelling tends to be particularly complex, and the greater the precision sought, the greater the complexity. Economic modelling gives greater clarity to the economic impacts of trade agreements, such as income levels and prices.[205] Economic models are commonly used by trade practitioners to assess the *ex ante* impacts of proposed reforms.[206] Two modelling methods – general equilibrium models and partial equilibrium models – are the most widely used assessment method in *ex ante* trade impact assessment.[207] General equilibrium models are comprehensive in nature, in that they link all sectors of the economy so that assessing the economy-wide impact of changes in trade policies is possible.

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205 Piermartini, R., and R. Teh, *Demystifying Modelling Methods for Trade Policy*, WTO Discussion Papers, No.10, World Trade Organization, Geneva, 2005.

206 For more detailed critiques of economic modelling and their relevance to *ex ante* assessment of trade agreements see: Kirkparick, C., Lee, N. and O. Morrissey, 'WTO New Round: Sustainability Impact Assessment Study', Phase One Report, Institute for Development Policy and Management and Environmental Impact Assessment Centre, University of Manchester, 1999; McCulloch et al, *op.cit.*, pp. 97f; Scrieciu, S., 'How Useful are Computable General Equilibrium Models for Sustainability Impact Assessment', *Working Paper Series No. 12/2005*, Impact Assessment Research Centre, University of Manchester (available at: http://www.sed.manchester.ac.uk/research/iarc/pdfs/iarc_wp12.pdf – accessed 12 January 2009).

207 Other models such as input-output models, cost-benefit analysis and econometric gravity models also exist; however, a review of literature suggests that GEM and PEM are the more relevant for *ex ante* impact assessment of trade agreements. United Nations, *Handbook on Integrated Assessment of Trade-Related Measures: The Agriculture Sector*, United Nations Environment Programme, New York and Geneva, 2005, pp. 49ff; United Nations Environment Programme (2001), *op.cit.*, pp.29f; Piermartini and Teh, *op.cit.*, p. 2; EC Handbook, *op.cit.*, p. 36.

They are particularly relevant to measuring economic impacts, although models can also be designed to measure environmental and social impacts. The trade reforms most susceptible to measurement through general equilibrium models are changes in tariff levels, subsidies or quantitative measures.[208]

Partial equilibrium models focus more narrowly on only one part of the economy, such as the impact of lowering a tariff covering wheat, without considering the effects that lowering that tariff might have on other parts of the economy. This distinguishes partial equilibrium models from general equilibrium models, which link all sectors in the model. The assumption behind partial equilibrium models is that the sector focused on has either a small or non-existent impact on the rest of the economy, or alternatively, that the rest of the economy has either a small or non-existent impact on the sector under examination. Given the more limited nature of partial equilibrium models, the data requirements are less significant. If an assessment seeks the impact of a change due to trade reform in a particular sector in a specific country, this model could be helpful.[209]

The second assessment technique is the *survey*. The term 'survey' can refer to the collection of both quantitative as well as qualitative information, depending on the technique used. Surveys, such as household surveys, provide a numerical description of opinions, attitudes or trends of a population through the study of a sample of that population.[210] However, surveys might also be qualitative and subjective, relying on random samples of country populations asking sets of standard questions on perceptions relating to the promotion and protection of human rights. Surveys can collect primary data through the use of questionnaires, face-to-face interviews, telephone interviews, suggestion boxes and structured observations, or alternatively rely on the analysis of secondary data such as a review of records, for example school records or census data. Surveys can be random, repeated over time to explore change, seasonal, or they could be iterative, beginning with a general survey which leads progressively to more in-depth surveys. Quantitative surveys tend to be structured, although surveys might also be semi-structured and even unstructured, the latter lending itself more to qualitative research.

Third, *causal-chain analysis* identifies and describes the significant cause-effect links between a proposed trade reform and the potential impact on the economy, environment or society and, in the present case, on the enjoyment of human rights.[211] Through causal chain analysis, the various cause-effect links are identified along the chain from the introduction of a trade reform to the enjoyment of a right by an individual and the capacity of the government and other actors to meet human rights obligations. The strength of causal-chain analysis rests on the quality of the explanation of the causal steps leading from a trade reform to the enjoyment of human rights. In this

208 Piermartini and Teh, *ibid.*, pp. 4, 7, 10f .
209 *Ibid.*, pp. 4f.
210 Creswell, *op.cit.*, p. 153.
211 Kirkpatrick,C. and N. Lee (Final Report to the European Commission), *op.cit.*, p. 31.

regard, it is important to explain the other factors that could affect each causal step along the chain, such as factors that might influence the abuse or the enjoyment of human rights that are not necessarily related to trade reform.

The fourth assessment technique is the *participatory case study*. The term 'case study' is loosely used to refer to many different forms of study and research. A case study might be exploratory, descriptive or explanatory. One definition of case study states that 'a case study is an empirical inquiry that investigates a contemporary phenomenon within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident'.[212] In the present context, a case study might investigate the effects of a proposed trade reform within the real-life context of a rural community. In this way, case studies tend to focus on particular sectors, particular communities, or particular groups such as a minority or disadvantaged group. Participatory case study techniques are a sub-set of case study methods which have particular resonance in the human rights field, given their capacity to involve individuals potentially affected by trade reforms in the assessment process. Methods range from information-sharing and consultation, to involved mechanisms for collaboration and empowerment that give people influence and even control over decisions.[213] However, relatively little work focuses on participatory assessment in the context of undertaking *ex ante* impact assessments of trade agreements.

Fifth, *expert opinion* is often the most frequently used and also the least formalized and sophisticated assessment technique in impact assessment.[214] Interviewing is a common form of collecting expert data. Interviewing can take a variety of forms, from structured formal questionnaires, to semi-structured or conversational interviewing. Interviews tend to yield qualitative information, the more so when they are only semi-structured. Indeed, the value of semi-structured, conversational interviews is to provide an overall focus on relevant issues while bringing out the interviewees personal reflections and experience in the area. Where expert opinion is sought, interviewees are often referred to as key informants, namely, individuals that have specialized knowledge of the issue under examination or who represent a particular group or viewpoint.[215]

212 Yin, R.K., *Case Study Research: Design and Methods*, Applied Social Research Methods Series, Vol. 5, Sage Publications, Thousand Oaks, California, Third Edition, 2003, p. 13.

213 For more information, see: Narayan, D., J. Rietbergen-McCracken, 'Participation and Social Assessment: Tools and Techniques', World Bank, United States of America, 1998; Banerjee, U.D., 'Participatory Assessments: A Mapping of Methods', United Nations Development Programme, New York, 2004. Kvale, S. and S. Brinkmann, *Interviews: Learning the Craft of Qualitative Research Interviewing*, Sage, California, 2009.

214 Kirkpatrick et al, 'Final report to the European Commission', *op.cit.*, p. 37.

215 See Kvale, and Brinkmann, *op.cit.*

Relevance of the five techniques to HRIAs

Economic modelling can be a useful technique in clarifying the future economic impacts of a trade agreement, such as changes in income and price levels, which can be important first steps in understanding the cause-effect relationships between the introduction of a trade measure – its economic impacts – and ultimately its human rights impacts. For example, understanding impacts on price levels is a first step in determining impacts on access to and affordability of essential goods and services and ultimately the enjoyment of relevant rights. However, modelling will generally have to be supplemented by other material in order to determine ultimate impacts on human rights. The focus of general equilibrium models on global impacts and economy and sector wide effects of trade agreements mean that results from these models are not always easy to disaggregate into effects on individuals or on particular human rights situations. This can be critical for HRIAs which have the goal of better understanding the real world experiences of individuals and communities and the enjoyment of their rights.

In this sense, partial equilibrium models might be more appropriate, given their sectoral focus, which could allow for more detailed and specific quantitative analysis. However, the assumption underlying partial equilibrium models that the impact of a trade agreement on other sectors is fixed might be unrealistic in many trade reform scenarios which introduce comprehensive changes to trade measures that generally lead to wide effects on the economy, environment and society which cannot be easily distinguished or ignored. An important factor to bear in mind in the use of economic models is the underlying assumptions. Economic models have been criticized for accepting uncritically an overly mechanistic free market-oriented and money reductionist approach to trade reform which fails to take into account ethical, interdisciplinary and a dynamic approach.[216] This naturally influences the results of a modelling exercise. This can be particularly relevant to HRIAs, given that HRIAs seek to assess the impact of free-market approaches on the rights of individuals, and in doing so, adopt a critical stance to trade theory and trade reform.

Surveys can be useful to HRIAs in seeking the voices of 'rights-holders' and 'duty-bearers' on opinions concerning the importance and desirability of particular aspects of trade agreements. While surveys are not participatory in the same way as face-to-face interviewing or participatory case studies, they have the advantage of increasing the number of individuals whose opinions are sought, increasing the geographical reach of the assessment, and collecting data more rapidly than some other assessment techniques that can be concentrated, dense and resource intensive. Moreover, surveys can be useful to mine for information and opinions which can in turn be supplemented by qualitative research techniques, such as participatory case studies, in order to give

216 Scrieciu, S, *op.cit.*

greater depth and context to some of the issues arising from the survey.[217] In this way, surveys provide a means to balance the need to consider the impact of trade agreements on 'rights-holders' and 'duty-bearers' with the imperative of providing information that can be generalized to a population in such a way as to be meaningful and convincing to trade policy-makers.

Causal-chain analysis is a simple to use and essential element of any impact assessment toolkit, including HRIAs. Causal-chain analysis can help in ensuring an adequately explained and justified link between real or potential changes in enjoyment of human rights and reform of particular trade measures. This is important, particularly given the many factors that can influence the enjoyment of human rights beyond macroeconomic policies. Identifying the causal links between trade reform and human rights enjoyment helps to isolate trade impact from other effects and to build a stronger case to develop rights-based trade policy. In cases where a rapid HRIA is necessary and resources are not available to undertake primary data collection and analysis, causal chain analysis helps to explain conclusions concerning the impact of trade agreements on human rights. In more detailed HRIAs, causal chain analysis provides the basis to identify hypothetical impacts of trade agreements on human rights, which are then tested through the use of other impact assessment techniques as discussed below. As causal-chain analysis generally relies on secondary materials, such as existing studies, reports, experiences in similar situations, expert opinion and so on, the reliability of the analysis also relies on the quality of those materials. Where time permits, causal chain analysis is generally applied in combination with other assessment techniques that produce primary data, although potentially a desk study could rely solely on causal-chain analysis.

Case studies can be useful to HRIAs by supplementing other methods such as statistical or survey methods of research in order to give some experience of real life reactions to trade reforms. Further, participatory methods respond to the particular requirements of collecting and analyzing human rights-related data. Much human rights knowledge is interpretive and contextual, rather than objective and universal, and qualitative participatory methods help to collect this sort of information. Participatory case study techniques might be useful when the aim of an assessment is to raise community awareness about a trade agreement and to empower individuals and communities to participate more closely in activities that affect them. However, participatory case studies are time-consuming and produce subjective and highly contextualized data which is not always relevant to *ex ante* HRIAs of trade agreements seeking to draw nationally relevant conclusions. For example, Yin notes that case studies are more appropriate to expand or generalize theories rather than enumerate

217 Department for International Development, 'Sustainable Lifelihoods Guidance Sheets: Vulnerability Context', No. 4.8 (available at: http://www.livelihoods.org/info/info_guidancesheets.html – accessed on 22 March 2008).

frequencies.[218] Statistical sampling procedures might provide a guide.[219] Where the population is relatively small, as is the case when assessing the impact of trade reform on a particular indigenous community, or on access to essential medicines by people with HIV, the sample might likewise be relatively small, allowing the effective use of participatory techniques. Where the issue is larger, for example, the impact of agricultural trade reforms on farming communities, the need to provide an adequate sample raises concerns of time and resources and a survey might be more appropriate.

Expert opinion might be relevant in several ways to *ex ante* human rights impact assessments: first, in choosing which assessment methods are appropriate to the application of the impact assessment methodology in any given situation; second, in confirming results in the screening and scenario building stages of the assessment methodology; third, in confirming cause-effect links in causal chain analysis; and fourth, in filling in gaps in data. In this way, experts might form part of an assessment team or might be external to the assessment, brought in to provide a second opinion or to provide primary data relevant to the assessment. Indeed, the assessment team is itself constantly exercising expert judgment throughout the assessment process and, in particular, in drafting the assessment report. One of the positive aspects of relying on expert opinion is that it is a relatively simple and timely way to collect data. However, expert opinion is of course easily open to criticism. Questions arise as to who constitutes an 'expert' and what is the value of, an 'opinion', which after all is subjective, albeit as a result of a deeper knowledge of or experience in, a particular field.

Criteria for choosing assessment techniques

While HRIAs will generally mix qualitative and quantitative methods and therefore rely on more than one impact technique, all five techniques will not necessarily be relevant to every assessment. The question still therefore now turns to the choice of assessment techniques relevant to any specific assessment exercise. The following criteria are relevant and each element in the methodology for the HRIA should be addressed in the final report:

a) *The stage of the assessment* – assessment occurs at several stages of an ex ante human rights impact assessment, most commonly during the screening or preliminary assessment stage, the full assessment stage and the stage of identifying recommendations. The screening stage normally relies on less complicated and rapid assessment procedures to ensure the elimination of less relevant trade measures from the assessment.

218 Yin, *ibid*., p. 10.

219 For example, the number of interview subjects in common interview studies is between ten and fifteen. If the purpose of the study requires a significantly larger figure, such as 1,000, then an alternative interview technique should be employed, such as a survey. Kvale and Brinkmann, *op.cit.*, pp. 113ff.

b) *The trade measure* – different trade measures require different assessment methods. As noted above, economic modelling is relevant to determining the price effects of modifications to tariffs, subsidies and quantitative restrictions, but not necessarily to changes in trade rules such as intellectual property protection.
c) *The human rights impact* – a case study approach might be more relevant to assess the level of participation in decision-making as it relates to trade, while statistical analysis could be more appropriate for assessing the availability and affordability of essential goods and services.
d) *The strength and weaknesses of the assessment technique* – both the benefits that each assessment technique offers to the HRIA as well as the weaknesses of the approach should be considered. The methodology section should address those weaknesses and explain how they are dealt with in the assessment, either through the combination of different techniques or in explaining the impact of those weaknesses on the assessment outcome.

In addition, it is important to consider the feasibility of particular assessment techniques given the specific context of the assessment exercise:

a) *Data availability* – data availability is one of the most problematic factors limiting an HRIA. Data might be sought from existing sources such as national Bureaus of Statistics and international databases or existing studies. Alternatively, data might not exist and therefore a decision must be made whether to collect new data or rely on secondary data in the form of existing studies. If the latter is used, it is important to ensure its reliability and validity.
b) *Time and resources* – time and resources differ from project to project. Often, ex ante assessments have only short time periods for completion as the results have to feed into sometimes rapidly moving policy-making and negotiation processes. Similarly, resources might also be tight, particularly where civil society organizations have limited funding but realize the importance of ensuring that human rights data is fed into a trade negotiation process.
c) *Skills capacity* – the effectiveness of an assessment depends significantly on the skills available to the group of professionals undertaking an assessment. While skills-training is always possible, time might not always permit each assessor to undertake additional training. Consequently, the choice of assessment method depends in part on the available skills – whether legal, social science, environmental, and so on. Skills limitation, as with time, resource and data limitations, should be identified clearly in the assessment so that the user of the assessment can fully understand the context and constraints facing the assessment and the conclusions drawn from the assessment.

Choosing case-specific assessment methods

The following steps should help to identify the most feasible and appropriate assessment methods for a specific impact assessment exercise.

1. *The trade measure under reform* – Describe the trade measures and the proposed reform of the trade measure under examination.
2. *The potential human rights impact* – Based on the impact categorization in section 3 of this Chapter, identify the potential impact (e.g. normative conflict, impact on enjoyment of a right etc) and identify which specific rights are affected (e.g. right to food, right to health etc).
3. *The cause-effect links* – Using logic and secondary materials, identify the cause-effect links between introduction of the trade measure and the right. Identify alternative factors that might affect the right and consider the extent to which the cause-effect links are valid and reliable. If the links are not valid and reliable, seek further information and explanations of the possible cause-effect links.
4. *The assessment methods* – Once the cause-effect links are valid and reliable, identify the available assessment methods to verify the links. Ask whether the assessment methods meet the requirements for human rights assessments (for example, whether they promote popular participation, disaggregate information etc). Are there sufficient assessment methods to verify the various cause-effect relationships? If not, can new methods be devised or can the cause-effect relationships be demonstrated using alternative methods?
5. *Data* – summarize the assessment methods and consider whether sufficient data are readily available. Ask whether it is possible to collect additional data to meet shortfalls. If not, can any of the steps from 1-4 be revised which would allow readily available data to meet data needs?
6. *Feasibility* – are assessment methods feasible given time, resources and skills?
7. *Summary* – summarize the final assessment package and commence the assessment.

6 CONCLUSION

Chapter II has established a methodology for *ex ante* human rights impact assessments of trade agreements. It has described trade measures and their potential to affect human rights and identified the trade sectors that should normally be examined when undertaking an HRIA. The methodology also provides a categorization of impacts of trade agreements on human rights, based on secondary materials related to the human rights and trade debate. The methodology then proposes a step-by-step process for undertaking HRIAs and establishes a process for data collection and analysis, identifying a mixed-methods approach that combines qualitative and quantitative approaches to data collection and analysis, a framework for selecting human rights indicators, as well as a set of five assessment techniques relevant to various stages of the HRIA process.

CHAPTER III
ASSESSMENT OF CAFTA: THE IMPACT OF INTELLECTUAL PROPERTY PROTECTION ON THE RIGHT TO HEALTH AND RELATED RIGHTS IN COSTA RICA

1 INTRODUCTION

Chapter III illustrates the methodology developed in Chapter II by undertaking a Human Rights Impact Assessment of the Dominican Republic-US-Central American Free Trade Agreement (CAFTA) on the enjoyment of human rights in Costa Rica. The Chapter follows the step-by-step methodology developed in Chapter II, following the various stages of 'preparation', 'screening', 'scoping', 'analysis', 'conclusions and recommendations' and 'monitoring and evaluation'. It identifies potential impacts according to the ten impact categories, chooses human rights indicators according to the criteria outlined previously, and analyzes impact relying on three of the six assessment techniques discussed in Chapter II. The results of the HRIA feed into the discussion on the original elements and benefits and risks of HRIAs in Chapter IV.

It is important to emphasize that the HRIA in the present Chapter is only an *illustration* of the methodology – of the problems faced and issues arising – developed in Chapter II. In other words, it seeks to demonstrate the methodology in practice with a view to deepening understanding of the methodology and the human rights framework, in turn assisting in the identification of the extent to which there is value in progressing further with HRIAs of trade agreements. This distinguishes Chapter III from a *test* of the methodology. Testing the methodology would be considerably more involved and would require the implementation of several HRIAs and a comparison of the results. It would determine whether the methodology achieves its stated aims. The research question underlying this thesis seeks to determine whether there is value in going further with HRIAs in the future, for example, through a complete test of the methodology, through a consideration of the benefits and risks of undertaking HRIAs of trade agreements.

It is also important to underline that the HRIA in Chapter III is not a complete assessment of the impact of CAFTA on the enjoyment of human rights in Costa Rica. While the 'screening' stage identifies several areas of CAFTA that might have positive or negative impacts on the enjoyment of human rights, the rest of the HRIA examines only one aspect of CAFTA, namely the impact of intellectual property provisions on access to medicines and human rights. This focus on only one aspect of CAFTA is justified on the basis that this is sufficient to provide an illustration of the methodology in Chapter II, as well as provide information to assist in the examination of the question underlying the thesis. A fuller assessment would not be necessary to meet this limited objective. I am justifying the focus on the impact of intellectual property on access to medicines and human rights on the basis that secondary materials reveal this

to have been one of the most contentious issues in a contentious debate concerning the potential impact of CAFTA.

Chapter III relies on the specific case of the impact of CAFTA on the enjoyment of human rights in Costa Rica for several reasons. First, an HRIA of the impact of CAFTA on human rights in Costa Rica could contribute to clarifying potential impacts of trade on human rights in what has been a highly-charged and contentious national debate. Costa Rica was the only country that took the unprecedented step of subjecting ratification of CAFTA to a national referendum in October 2007, which resulted in a narrow majority in favour of ratification. While it is too late to change the content of CAFTA, an HRIA could provide useful information to clarify potential impacts on human rights in Costa Rica, which could in turn influence the implementation phase, respond to both the supporters and critics of CAFTA by providing greater clarity to the debate, as well as provide baseline information for a future *ex post* assessment of CAFTA after some years of implementation.

The second reason to focus on the impact of CAFTA in Costa Rica relates to the existence of reliable data. The particularly contentious nature of the impact of CAFTA in Costa Rica has led to the generation of a considerable amount of data on the potential impacts of CAFTA, even though this data had to be supplemented with further data through key informant interviews in order to complete the assessment. More generally, Costa Rica has developed sophisticated and reliable systems of data collection and analysis, including in relation to the issues under examination in this Chapter. The existence of reliable data has been an important factor in ensuring that Chapter III provides a relatively sound illustration of the HRIA methodology.

A third reason for focusing on the impact of CAFTA on human rights in Costa Rica is to help respond to a request by the Committee on Economic, Social and Cultural Rights. In November 2007, the Committee considered the periodic report of Costa Rica and expressed concern that the country's ratification of CAFTA would affect the ICESCR's provisions of relevance to traditional agriculture, labour rights, access to health, social security and the intellectual property regimes protecting, inter alia, access to generic medicines, biodiversity, water and the right of indigenous communities associated to these resources. In this regard, the Committee requested the Government to assess the potential impact of the agreement on economic, social and cultural rights.[1] It is hoped that the Assessment will assist both the Costa Rican Government respond to this request, as well as the Committee in pursuing its work on the impact of trade agreements on human rights.

1 United Nations, 'Concluding Observations of the Committee on Economic, Social and Cultural Rights (Costa Rica)', Committee on Economic, Social and Cultural Rights, (E/C.12/CRI/CO/4: January 2008: para. 48).

2 STEP ONE: PREPARATION

The Republic of Costa Rica is situated in Central America and has a population of 4.3 million, 2.1 million of whom live in the capital, San José. The inhabitants are almost entirely of European descent with very small minorities of African, Chinese and Indigenous descent, as well as a minority of between ten to fifteen percent of Nicaraguans. The official language is Spanish with a small English Creole speaking minority in the East. It is a democratic Republic with universal suffrage and voting is compulsory for those over eighteen years of age. Costa Rica abolished the military upon the adoption of the Constitution in 1949. The UNDP Human Development Report ranks Costa Rica at number 48 in its index, considering it as having high human development.[2] The economy is largely driven by services supplemented by some industrial goods and to a lesser extent agricultural goods. Costa Rica plays an active role in international fora, including in the areas of human rights and in trade, and conscientiously implements its international commitments at home.

Costa Rica is generally considered a good international citizen in the area of human rights. Costa Rica has ratified six of the nine core UN human rights treaties.[3] Costa Rica has also ratified regional human rights treaties including the American Convention on Human Rights, and was the first country to recognize the jurisdiction of the Inter-American Court of Human Rights. It has been subject to relatively few complaints to the Inter-American Commission on Human Rights and the Court.[4] Costa Rica is now up-to-date in its reporting obligations in relation to human rights treaties, although it has been late, sometimes considerably late, in its reporting previously. Costa Rica has issued a standing invitation for Special Procedures of the Human

2 United Nations, *Fighting Climate Change: Human Solidarity in a Divided World*, Human Development Report 2007/2008, United Nations Development Programme, New York, 2007, p. 229.

3 Costa Rica has signed the Convention on the Rights of Persons with Disabilities, its Optional Protocol as well as the International Convention for the Protection of All Persons from Forced Disappearance. The only core treaty that Costa Rica has neither signed nor ratified is the Migrant Workers Convention. Costa Rica also allows individual communications in relation to the ICCPR and CEDAW and was an active participant in the negotiations on an individual communications procedure in relation to ICESCR. See the website of the UN Office of the High Commissioner for Human Rights (available at: http://www2.ohchr.org/english/bodies/ratification/index.htm – accessed 15 January 2009). Costa Rica has ratified many of the regional human rights treaties, including the American Convention on Human Rights and the Additional Protocol to the American Convention on Human Rights on Economic, Social and Cultural Rights. See the website of the Organization of American States (available at: http://www.oas.org/ – accessed 15 January 2009). Costa Rica is home to the Inter-American Court of Human Rights as well as the Inter-American Institute.

4 In addition to the petitions system established under the Convention, Costa Rica recognizes, without condition, the competence of the Inter-American Commission on Human Rights to receive and consider inter-state complaints and the jurisdiction of the Inter-American Court of Human Rights in all matters relating to the interpretation and application of the Convention. Costa Rica has also ratified the Additional Protocol to the American Convention on Human Rights in the area of Economic, Social and Cultural Rights.

Rights Council although the only Special Rapporteur to have visited Costa Rica in the last ten years has been the Special Rapporteur on Toxic Wastes.[5]

Nationally, Costa Rica has a long tradition of stable democracy and has strong national institutions and comprehensive recognition of human rights. The President heads the Executive, Parliament consists of only one chamber, the Legislative Assembly, and there is an independent judiciary comprising a Supreme Court of Justice and a Constitutional Court that reviews the constitutionality of legislation and executive decrees. Elections are supervised by an independent authority, the Supreme Electoral Tribunal. There is a national human rights institution, the Defensoría de los Habitantes, which received an 'A' rating from the Coordinating Committee of National Institutions for the Promotion and Protection of Human Rights (ICC) in 1999; this was renewed in 2006.[6]

The Constitution explicitly recognizes civil, cultural, economic, political and social rights, although in relation to some economic, social and cultural rights the Constitution identifies obligations on the State rather than specific rights. Under the Constitution, no less than six percent of the Gross Domestic Product must be spent on public education.[7] A review of Costa Rica's human rights record does not reveal any grave or systematic violations of human rights. Most human rights issues concern discrimination and equality between men and women, including concerns related to violence against women, and unequal pay for women employees. Migrant workers, particularly Nicaraguans and Colombians, suffer racial discrimination and face restrictions on joining trade unions and on social security coverage in some areas. Other problems include prolonged pre-trial detention and conditions of detention, discrimination on the basis of religion in the area of marriage as only Catholic marriages have civil effect, restrictions on journalists for reasons of protecting officials, forced evictions, and insufficient protections for trafficked people. Sex tourism has also become a concern and, as noted above, the Committee on Economic, Social and Cultural Rights has expressed concern about the impact of CAFTA on human rights.[8]

Costa Rica also projects an image of the good international citizen in the area of trade, actively engaged in the process of strengthening the international trading system and diligently complying with its international commitments. Costa Rica is a founding Member of the WTO and has actively pursued free trade agreements in the region.[9]

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5 Website of the UN Office of the High Commissioner for Human Rights (available at: http://www.ohchr.org/EN/countries/LACRegion/Pages/CRIndex.aspx – accessed 15 January 2009).

6 See the website of the National Human Rights Institutions Forum (available at: http://www.nhri.net/2007/List_Accredited_NIs_Dec_2007.pdf – accessed 15 January 2009).

7 Political Constitution of the Republic of Costa Rica, article 78.

8 See United Nations, 'Concluding Observations of the Human Rights Committee', November 2007, (CCPR/C/CRI/CO/5); United Nations, 'Concluding Observations of the Committee on Economic, Social and Cultural Rights', January 2008, (E/C.12/CRI/CO/4).

9 It has a free trade agreement with Panama that dates back to 1973 and one with Mexico from 1995. Since 2000 Costa Rica has negotiated agreements with Canada, Chile, the Dominican Republic and the Caribbean Community (CARICOM). In 2004, Costa Rica concluded CAFTA. In 2007, Costa Rica embarked

The Government perceives economic growth through increasing exports in goods and services as a key strategy for development and poverty reduction. An overarching national policy is to promote, facilitate and consolidate the integration of the country into the global economy, in a manner that is consistent with its economic and social objectives.[10]

The Costa Rican economy generally displays strong performance. In spite of rises in oil prices, the economy expanded at an average rate of 4.9 percent between 2001 and 2005, due principally to export and investment activity, although inflation is relatively high, reaching 14.1 percent in 2005. Costa Rican trade, imports as well as exports, has increased since 2001, although more slowly than during the 1990s. In the period 2001-2006, exports grew at an average rate of 10.46 per cent, reaching a level of 17.9 per cent growth in 2006, and a record total of US$8.215 billion. From 2001 to 2005, per capita gross domestic product (GDP) climbed 12.8 percent, reaching just over US$4,600 in 2005. However, Costa Rica suffers from a relatively high fiscal deficit and deteriorating terms of trade. In particular, while exports increased, so too did imports, inflating the trade deficit. Much of this has been due to increases in oil prices. Increased trade in services and investment has provided partial relief. The government has sought to respond to this challenge by reducing public expenditure and by promoting economic growth, particularly through trade and investment and tax reform. The total public debt-to-GDP ratio in 2006 was 55 percent, a figure recognized as relatively high. Public external debt servicing represented 4.4 percent of goods and services exports in 2005, which was a reduction from the level of 6.7 percent in 1999.[11]

Trade in goods increased on average by 10.46 percent from 2001-2005, comprising mainly manufactured goods. Manufactured goods comprise around 69 percent of all exports and 80 percent of imports. The most important industrial goods exported are integrated circuits and computer parts, medical equipment and devices as well as textiles. The presence of Intel in Costa Rica has had a significant impact on the economy. The most significant manufactured imports are integrated circuits and electronic micro-assemblies, chemicals and fuel. Agricultural trade also grew over the same period comprising 32.7 percent of exports in 2005. The most significant agricultural exports are bananas, followed by pineapples, and flowers, as well as coffee, melons, manioc and sugar.[12]

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on negotiations for an Association Agreement with the European Union which will cover trade and investment as well as other issues, including political dialogue on human rights. Costa Rica has investment agreements in force with Argentina, Canada, Chile, China, Czech Republic, France, Germany, Korea, the Netherlands, Paraguay, Spain, Switzerland and Venezuela. At the same time, legislative approval is pending for agreements with Ecuador, Bolivia, Finland, Belgium and Luxembourg. World Trade Organization, 'Minutes of Meeting', Trade Policy Review, Costa Rica, (WT/TPR/M/180: paras 30-32).

10 World Trade Organization, 'Trade Policy Review', Report by Costa Rica, March 2007, (WT/TPR/G/180: para. 11).

11 World Trade Organization, 'Costa Rica', Report of the WTO Secretariat to the Trade Policy Review Mechanism, (WT/TPR/S/180/Rev.1).

12 *Ibid*, paras 25-31.

Services have tended to play a significant role in trade over recent years. The most important service sector is tourism, including restaurants and hotels, followed by business services, transport, computer and information services.[13] The flow of foreign direct investment (FDI) to Costa Rica has also increased by 70 percent from 2001 to 2005 with an average annual flow of US$670 million. The estimated FDI for 2006 was US$1,410.8 million. Costa Rica is a net recipient of FDI. Costa Rica has sought to attract high quality FDI in the electronics industry, the medical devices sector, information technology-based services and tourism through lifting taxes and establishing free trade zones[14] which has assisted in attracting companies such as Intel, Pfizer, Baxter, Conair, Abbot Laboratories, Chiquita Brancs, and Merck Sharp & Dohme amongst others. A free investment zone has had a role in encouraging increased investment, attracting almost half of the investment over the 2001-2005 period. The manufacturing sector, particularly electronics and pharmaceuticals, have attracted a significant portion of FDI, followed by the tourism sector.[15]

The US is Costa Rica's main trading partner and also represents the principal country of origin of FDI. The other countries in the region (taken as a whole) and the European Union are the second and third principal trading partners respectively, with increases in trade with Asia, in particular China, in recent years. While exports and imports to and from the US have increased from 2001 to 2005, the relative share of US trade has decreased in relation to other trading partners.[16] Nonetheless, the US remains Costa Rica's principal trading partner, highlighting the potential significance of CAFTA to Costa Rican development.

Discussions on a possible free trade agreement between the US and Central America began in 2001, the negotiation process began in January 2003 and the Parties signed it on 28 May 2004. CAFTA comprises 22 chapters covering the themes of trade in goods and services, intellectual property protection, investment, labour, environment as well as procedural issues such as dispute settlement. Its objectives are essentially of a commercial nature, and include encouragement of the expansion and diversification of trade between the parties, the elimination of barriers to trade, the promotion of conditions of fair competition, and the establishment of a framework for bilateral, regional and multilateral cooperation to enhance the effects of the Agreement. The adoption of CAFTA gave rise to a heated debate in Costa Rica which led to a referendum on 7 October 2007, the first in Costa Rica's history, to decide whether the country should ratify the agreement. The vote in favour of ratification won by a small margin and Costa Rica proceeded to make the necessary legislative changes required for implementation. The final measures were adopted in December 2008.

13 *Ibid.*, para. 32.
14 Report by Costa Rica to the TPRM, *op.cit.*, para. 7.
15 WTO Secretariat Report for Costa Rica, *op.cit.*, paras 33-35.
16 *Ibid.*, para. 30.

3 STEP TWO: SCREENING

The 'screening' stage identifies those trade measures in CAFTA that are more likely to have significant impacts on the enjoyment of human rights and therefore warrant assessment. 'Screening' relies on the use of secondary materials to identify the likely cause-effect relationships between the introduction of CAFTA and human rights and their likely significance. Secondary resources are drawn from governmental, inter-governmental, human rights bodies and non-governmental sources, chosen to reflect a range of views on CAFTA. In terms of governmental sources, the 'screening' stage relies on an independent report by eminent experts, commissioned by the Government of Costa Rica, were mandated to examine the pros and cons of the agreement.[17] Reports of the World Bank, Inter-American Development Bank and the International Labour Office provide information from inter-governmental sources.[18] The Concluding Observations of the Committee on Economic, Social and Cultural Rights and a report of the Defensoría de los Habitantes, the Costa Rican national human rights institution, provide sources of information from human rights bodies.[19] Materials from civil society are drawn from respected international non-governmental organizations, namely the Center for International Environmental Law, Human Rights Watch and 3D-Trade, Human Rights, Equitable Economy.[20] With the exception of the reports of

17 Comisión de Notables, *Informe Final de Carácter General no Vinculante al Presidente de la República sobre el Tratado de Libre Comercio entre Centroamérica, República Dominicana y Estados Unidos de América*, 16 de setiembre de 2005, San José, Costa Rica.

18 World Bank, 'DR-CAFTA: Challenges and Opportunities for Central America', Central America Department and Office of the Chief Economist Latin America and Caribbean Region, World Bank, (available at: http://siteresources.worldbank.org/LACEXT/Resources/258553-1119648763980/DR_CAFTA_Challenges_Opport_Final_en.pdf – accessed 11 February 2009); Todd., J., P. Winters and D. Arias, *CAFTA and the Rural Economies of Central America: A Conceptual Framework for Policy and Programme Recommendations*, Economy and Sector Study Series, Inter-American Development Bank, Washington D.C., 2004; Granados, J., Z. Vodusek, A. Barreix, J.E. López Córdova, and C. Volpe, *Costa Rica: Ante un Nuevo Escenario en el Comercio Internacional*, Banco Interamericano de Desarrollo, Instituto para la Integración de America Latina y el Caribe, Sector de Integración y Comercio, Documento de Trabajo 32, Washington D.C., USA, 2007; Ernst, C., and D. Sánchez-Ancochea, *Offshoring and Employment in the Developing World: The Case of Costa Rica*, International Labour Office, Employment Sector, Employment Working Papers, No. 4, Geneva 2008; Jenkins, M., *Economic and Social Effects of Economic Processing Zones in Costa Rica*, ILO Working Paper No. 97, International Labour Office, Geneva.

19 United Nations, 'Concluding Observations of the Committee on Economic, Social and Cultural Rights (Costa Rica)', Committee on Economic, Social and Cultural Rights, (E/C.12/CRI/CO/4: January 2008: para 48); Defensoría de los Habitantes de la República, 'Consideraciones sobre la salud pública y bioética en materia de propiedad intelectual y medicamentos en el Proyecto de Ley de Tratado de Libre Comercio República Dominicana-Centroamérica-Estados Unidos', San José, Costa Rica, (available at: http://www.notlc.com/files/TLC_Anexo_Medicamentos.doc – accessed 6 October 2008).

20 Center for International Environmental Law, 'Separate Comments of TEPAC Members on the US-Central American Free Trade Agreement (CAFTA), William Butler (Board Member, Audubon Naturalist Society), Rohda Karpatkin (President Emeritus, Consumers Union of U.S., Inc.), Daniel Magraw (President, Center for International Environmental Law), Durwood Zaelke (President, Institute

Human Rights Watch and 3D-Trade, Human Rights, Equitable Economy, these materials did not consider the impact of CAFTA explicitly on human rights. However, the materials provide information upon which it is possible to make preliminary conclusions in relation to the likely impacts on human rights and their significance.

All the materials tended to focus on a range of macroeconomic, developmental and poverty-related issues. Of more specific relevance to the present exercise are the commentaries in relation to the following areas: the impact of CAFTA on employment, particularly in the agriculture, textile and manufacturing sectors; the impact of liberalization of agricultural trade on food security and on the livelihoods of farmers; the impact of liberalization of the telecommunications and insurance sector on universal provision of essential services; the impact of the investment chapter on investors' duties towards human rights; the impact of the intellectual property chapter on access to medicines, traditional knowledge and biodiversity, and on access to educational materials. Table III.1 summarizes the commentary and identifies potential impacts on human rights. The first column identifies the relevant chapters in CAFTA, the second column sets out the relevant human right or rights potentially affected by the Chapter. On the basis of the background materials, the third column identifies the likely direction or directions of the impact as well as the significance of the impact using a scale from '–2' (significantly negative impact) to +2 (significantly positive impact). The fourth column provides a commentary to explain the conclusion in column 3 on the 'likely' impact and the 'significance' of that impact.

As noted in the introduction, the present assessment does not attempt a full analysis of CAFTA, but instead only illustrates the Part Two methodology in practice through the analysis of one aspect of CAFTA on human rights. While many impacts of CAFTA are quite ambiguous, concern over the impact of intellectual property protection appears to be more pronounced. Specifically, human rights bodies and groups have drawn particular attention to the potential impact of intellectual property protection on access to medicines. Given the specific focus of human rights groups and bodies on the impact of intellectual property protection on access to medicines, the rest of the assessment focuses uniquely on this area. However, it is worth noting that a full assessment would also consider other aspects of CAFTA set out in Table III.1, such as the impact of agricultural trade reform on food security and rural livelihoods, and the impact of strengthened copyright protection on access to educational materials.

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for Governance and Sustainable Development)', 18 March 2004, (available at: http://www.ciel.org/Publications/TEPAC_CAFTA_18Mar04.pdf – accessed 15 January 2009); Human Rights Watch, *The United States-Dominican Republic-Central America Free Trade Agreement Falls Short on Workers' Rights*, Human Rights Watch written testimony submitted to the US House of Representatives Committee on Ways and Means, April 2005; Goodman, Z., 'Costa Rica: Strengthening Patent Laws, Weakening Human Rights', 3D – Trade, Human Rights, Equitable Economy, February 2008 (available at: http://www.3dthree.org – accessed 11 February 2009).

Table III.1 – Screening: CAFTA			
CAFTA provisions	**Human rights issue**	**Signifi-cance**	**Comment on the basis of secondary materials**
Agricultural trade (chapter 3 National Treatment and Market Access; chapter 4 – Rules of Origin; chapter 6 – Sanitary and Phytosanitary Measures)	1. Protection of the right to an adequate standard of living and right to take part in cultural life for small farmers and people in rural communities 2. Right to adequate food for Costa Ricans	+1/–1	The diversified nature and structure of Costa Rican agriculture with the growing dominance of larger producers places Costa Ricans in a relatively good position to absorb shocks from agricultural trade reform. *Exports* should benefit from a consolidation of US preferential treatment under the Caribbean Basin Initiative although, with the exception of some additional benefits in sugar, this maintains the status quo. Food safety standards might increase the burden on exporters but dominance of larger producers in the export sector should be able to absorb this. Costa Ricans should benefit from cheaper *imports* of food which in many cases do not compete with Costa Rican producers. A special agricultural safeguard should protect against high levels of food imports. Subsistence farmers producing for local consumption should not be affected directly by changes in international trade. This explains the significance criteria of (+1): Potential problems arise for *small farmers*, particularly in traditional areas of rice, maize and beans. They will have to face imports of cheaper US subsidized products (at artificially low prices because of very high US subsidies) and lower levels of government support. This will likely affect their standard of living and traditional lifestyles and they might not have the resources to adapt without assistance. It might increase the strains on government capacity to compensate them for loss of livelihoods. In terms of significance, agriculture is of declining importance to the Costa Rican economy and much production is in the hands of larger producers. However, smaller producers, although less significant in number than in some other countries, could come under strain suggesting negative impacts on a limited section of the population might be possible. This explains the significance criteria of (–1).
Labour (CAFTA generally and chapter 16 – labour)	1. Impact of CAFTA on employment 2. Protection of workers' rights in trade-related industries	0	Impact on *employment* is likely to be mixed but not significant (therefore significance criteria of 0). The sectors more likely to be affected are: agriculture, textiles, tourism, high technology and the public sector, particularly telecommunications and insurance. In agriculture, there could be job losses and gains depending on policies to move into non-traditional agricultural production and areas not competing with US production; in textiles, competition from China outweighs any potential benefits from CAFTA; employment gains could result from investment in

			tourism services although other areas of FDI have not resulted in significant employment gains; increases in high technology exports might lead to employment gains although stronger intellectual property protection could lead to losses in the generic pharmaceutical industry. Opening of telecommunications and insurance sectors could lead to job losses. Consequently, there are likely to be gains and losses in employment. In relation to *labour standards*, workers' rights in export industries and in export processing zones tend to be respected and are even higher than national averages. There is concern that the chapter on labour in CAFTA fails to recognize some workers' rights (such as non-discrimination), lacks sufficient enforcement, and is focused on trade impacts rather than on impacts of trade on labour standards. Costa Rica has effective protection of labour standards and inclusion of a chapter on labour should not have any negative impact on national standards or their protection.
Intellectual property protection (chapter 15)	1. Impact of test data protection, patent restoration and 'linkage' on access to medicines 2. Impact of UPOV on biodiversity and food and public health 3. Impact of copyright protection on access to education materials	– 2	While Costa Rica already provides patent protection over pharmaceutical products, strengthened protection of test data as well as restoration of patents due to administrative delays and administrative requirements on the Ministry of Health in relation to protecting patents could effectively lengthen the life of patents, strain government capacity and lead to price rises for essential medicines. The requirement to ratify UPOV 91 (Convention on Plant Variety Protection of 1991) has raised concerns that protection of the creators of plant varieties does not adequately take into account the imperative of ensuring prior informed consent and equitable sharing of benefits for the use of traditional knowledge over plants. This can affect indigenous communities, and has raised concerns over the impact of plant variety protection over access by farmers to new crop varieties. The Chapter limits the prerogative of educational institutions to circumvent without authority technological measures that create access to educational materials to only access for reasons of purchase – thus access to such materials (without authority) for educative purposes is not permitted. This could restrict access to educational materials and affect quality of education. Human rights bodies and civil society groups have placed significant focus on the potential impact of intellectual property protection with little evidence of benefits flowing to Costa Rica. There are potentially all round negative implications flowing from the IP chapter justifying a significance criteria of (–2).

Investment (chapter 10)	1. No recognition of human rights responsibilities of investors; 2. Potential constraint on government regulatory capacity to promote public health due to expropriation provisions and performance requirements; 3. Procedural aspects of investor-to-state dispute settlement. 4. Potential to increase available resources for realization of ESCR	–1/+1	Chapter 10 tends to strengthen both the definition of investor rights as well as their justiciability without defining investor obligations towards human rights. The investor-to-state dispute settlement procedure marks a tendency to pass over domestic courts raising questions about the rule of law. Possible impact on public health regulations where these might force changes on investors (eg to improve environmental protection after an investment has been made) is unclear although it has raised concern previously under NAFTA. This justifies a significance criteria of (–1). On a positive note, procedures appear to allow *amicus* briefs from civil society in investor-to-state disputes. To the extent that the Chapter increases investment, this assists the government in its stated plan to achieve development and poverty reduction through economic growth and investment. Investment has tended to have a positive impact on economic growth in Costa Rica which could have flow-on positive impacts for human rights if managed correctly. This justifies a significance criteria of (+1).
Insurance (chapter 12), Telecommunications (chapter 13)	1. Competition in the sectors might detract from the current principle of universality. 2. Competition might reduce current unprofitable pro-poor tariff schemes	–1	The liberalization of the insurance sector has the potential to affect some forms of social security although the social security services of the Caja Costarricense de Seguridad Social (CCSS) – which provides social security services in relation to health care - are excluded. Liberalization of insurance and telecommunications potentially threaten the universality of services which are based on the principle of social solidarity. Current universal coverage might be threatened, particularly where services are provided for below-profit tariffs, and a two-tiered system of service provision might result. This justifies a significance criteria of (–1). However, private sector competition in telecommunications might also lead to more competitive pricing and better services. This justifies a significance criteria of (+1)

4 STEP THREE: SCOPING

4.1 Introduction

Having narrowed the focus of the assessment in the 'screening' section to the impact of the intellectual property provisions in CAFTA on access to medicines and human rights, the 'scoping' section provides detailed information on:

- Intellectual property protection in Costa Rica related to access to medicines, covering international obligations in CAFTA as well as the current steps the Government is taking to implement CAFTA;
- Human rights and access to medicines in Costa Rica, including the normative and policy frameworks;
- Potential impacts of CAFTA on access to medicines and human rights according to the classification of impacts identified in the methodology;
- The choice of assessment techniques including justifications of the choice according to the criteria in the methodology;
- Human rights indicators.

Section 4.2 explains the intellectual property protection provisions affecting access to medicines included in CAFTA, as well as the various Costa Rican laws implementing those provisions. While the section is long, it is important to set out the provisions in detail in order to understand exactly what CAFTA does and does not require as well as how CAFTA has been implemented in Costa Rica, in order to understand how these provisions might affect access to medicines in the future.

4.2 Intellectual property protection and access to medicines in CAFTA

Introduction

Prior to negotiating CAFTA, Costa Rica had already undertaken obligations to provide intellectual property protection to pharmaceutical products as a result of its adoption of the WTO's TRIPS Agreement. The relevant provisions of that agreement are set out in Annex Two. Chapter 15 of CAFTA deals with intellectual property protection and, in several ways, goes beyond the requirements in the TRIPS Agreement. These provisions are referred to as TRIPS plus provisions. It is important to underline that the present HRIA examines the impact of only CAFTA's intellectual property protection on access to medicines, and not the impact of intellectual property protection generally. In other words, the HRIA accepts as a baseline that Costa Rica has already undertaken commitments to provide intellectual property protection to pharmaceuticals and is concerned only with measuring the impact of the additional protection included in CAFTA on access to medicines and human rights. A broader discussion of the

impact of intellectual property protection on access to medicines is beyond the scope of the present HRIA.

This sub-section does three things. First, it sets out the relevant provisions in CAFTA; second, it identifies the ways in which they go beyond the TRIPS Agreement; and, third, it sets out how Costa Rican has implemented the TRIPS plus provisions in its legislation.

Requirements for patents

CAFTA appears to relax the requirements for the grant of patents. The TRIPS Agreement requires patents to be available for any inventions that are 'new', 'involve an inventive step' and are 'capable of industrial application'. CAFTA includes the same requirements but notes that a Party may treat the terms 'inventive step' as 'non-obvious' and the term 'capable of industrial application' as 'useful'.[21]

Patent restoration

The TRIPS Agreement sets the minimum term for a patent at twenty years. The agreement does not include any reference to extending the twenty year patent term due to administrative delays in the grant of the patent or in marketing authorization for pharmaceutical products. Costa Rica's 'Ley de Patentes de Invención, Modelos de Utilidad, y Dibujos Industriales' of 1983 (Law 6867) provided the first law covering intellectual property protection of innovations and designs in Costa Rica which was revised in 2000 (Law 7979) in light of its commitments made under the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights. While previously patents were granted for a term of one year, the Law now stipulates the patent term as 20 years, in conformity with the TRIPS Agreement.

CAFTA goes beyond the requirements of the TRIPS Agreement and requires patent restoration in case of administrative delays. Article 15(6) requires the Government to adjust the term of a patent to compensate for unreasonable administrative delays that have occurred either: first, in the process of granting the patent; or second, in the process of granting marketing authorization for pharmaceutical products covered by patent. First, in relation to *delays in granting patents*, CAFTA states that an unreasonable delay occurs if the process takes at least five years from the date of filing the application in Costa Rica or three years after the request for examination of the application, whichever is later. Periods attributable to the actions of the patent appli-

21 Correa, C., *Guidelines for the Examination of Pharmaceutical Patents*, World Health Organization/ United Nations Conference on Trade And Development/International Centre for Trade and Sustainable Development, 2008, p.4. Correa notes the open nature of the TRIPS requirements for patentability and identifies the interpretation of 'capable of industrial application' as being merely 'useful' as a more lenient test which could increase the number of pharmaceuticals under patent and therefore restrict competition.

cant are not included in the determination of delays. The article leaves open the period of patent restoration as a result of the delay, which means each Party can determine the period for itself.

Second, in relation to *delays in the grant of marketing authorization* for a pharmaceutical product, the Government must prolong the patent term to compensate for unreasonable curtailment of the patent term resulting from the marketing authorization process. The article does not indicate the length of time that constitutes an 'unreasonable curtailment'. As with delays in the grant of patent, the article leaves open the period of patent restoration as a result of delays in the grant of marketing authorization for determination by each Party.

In order to comply with the requirements of CAFTA, Costa Rica amended the Patent Law 6867 in March 2008 by the Ley Modificación de Varios Artículos de la Ley de Marcas y Otros Signos Distintivos, Ley No. 7978, de la Ley de Patentes de Invención, Dibujos y Modelos Industriales y Modelos de Utilidad, No. 6867 y de la Ley de Biodiversidad, No. 7788 (Law 8632) which in turn was modified by the Ley de Reforma, Adición y Dereogación de Varias Normas Que Regulan Materias Relacionadas Con Propiedad Intelectual (Law 8686) of 21 November 2008 so as to ensure Costa Rican patent law conformed to CAFTA and met the certification requirements of the US. The following sets out the current patent law relevant to the implementation of the patent restoration provisions in CAFTA.

a) *Patent term*: The length of patent protection is twenty years.
b) *Definition of delay in grant of patent*: In keeping with CAFTA, patent restoration for administrative delays is allowed. A delay in the grant of patent is calculated as five years from the date of application and three years from the date of examination of the patent application.
c) *Definition of delay in marketing authorization*: In relation to delays in marketing authorization, unlike CAFTA, a delay is actually defined, namely, where marketing authorization takes more than three years from the date of submission of the application to the health registry.
d) *Definition of restoration time for delays in grant of patent*: The time for patent restoration is calculated as one day for every one day of delay. The maximum time for patent extension as a result of administrative delays in the grant of patent or marketing authorization is 18 months.
e) *Definition of restoration time for delays in grant of marketing authorization*: The time for patent restoration due to delays in marketing authorization is calculated as one day for every day of delay with a maximum of 18 months.
f) *No accumulation of patent restoration terms*: Where delays occur in both the grant of patent and the marketing authorization, it is assumed that patent restoration cannot be accumulated for both. The maximum time for patent restoration appears to be 18 months.

g) *Time to claim patent restoration*: The patent owner has three months from the date of the grant of patent or the data of approval on the health registry to request patent extension and the request must be in writing.
h) *Exclusion of patent restoration*: Patent restoration is excluded where the patent life over the product in question is 12 years or more from the date of the grant of marketing authorization. In such cases, patent restoration would not be possible.

Table III.2 – Patent restoration

TRIPS	CAFTA	Costa Rican legislation
Minimum patent term of 20 years for pharmaceutical products.	Reaffirmation of the TRIPS Agreement including, by implication, minimum patent term of 20 years.	Minimum patent term of 20 years.
	Restoration of patent term in the case of delays in the grant of patent – namely where grant takes at least (1) five years from date of application (2) three years from request for examination.	Conforms with CAFTA. In addition, restoration of one day for each day of delay granted with maximum restoration of 18 months.
	Restoration of patent term in the case of unreasonable curtailment in marketing authorization – unreasonable curtailment not defined.	Conforms with CAFTA. In addition: (1) unreasonable curtailment defined as more than three years from date of filing for marketing authorization. (2) Restoration of one day for each day of delay with maximum restoration of 18 months.
		(1) No accumulation of patent restoration terms for delays in grant of patent and marketing authorization. (2) Patent owner has three months to request patent restoration. (3) Patent extension excluded if patent has 12 years or more left from the date of grant of market authorization.

Protection of test data

In most countries, the national drug marketing authorization, such as the Ministry of Health, requires producers to provide test data demonstrating the safety and efficacy of a drug, as part of marketing authorization of pharmaceuticals, a process that is independent of the grant of patents over the products. A practice has developed whereby a generic producer relies on the test data already provided by an innovator

pharmaceutical company over the brand drug when seeking marketing authorization of a generic version of a drug. Alternatively, the Ministry of Health might rely on its previous approval of the original innovator drug for the approval of the generic where bioequivalence is demonstrated. In some countries, the Ministry of Health might rely on marketing authorization granted overseas, such as by the US Food and Drug Authority (FDA) or in the EU by the European Medicines Agency (EMEA) as a means of granting marketing authorization to a bioequivalent drug – either a branded drug or a generic drug. This saves the Ministry of Health having to undertake tests on efficacy and safety that marketing authorities have already undertaken previously in other countries. It is important to note that test data takes considerable time to amass – for example, through testing in laboratories and eventually testing on animals or on patients – and can involve considerable additional cost to the pharmaceutical producer. When tests reveal that a new pharmaceutical product is either not safe or not efficient and marketing authorization is elusive, time and resources are not always recompensed.

CAFTA has included specific rules on the protection of test data supplied for reasons of pharmaceutical marketing authorization procedures that go beyond the requirements of the TRIPS Agreement. The provisions in the TRIPS Agreement and CAFTA are technical in nature and require a close reading in order to demonstrate how CAFTA goes beyond the requirements in the TRIPS Agreement. This section proceeds on the basis of first, outlining the relevant provisions in CAFTA and second, comparing them with the relevant provisions in the TRIPS Agreement.

CAFTA provides five years protection of undisclosed test data concerning the safety and efficacy of a pharmaceutical product that the producer has supplied as a condition for receiving marketing authorization of a new pharmaceutical product. In such cases, a Party to CAFTA shall not permit third persons to seek marketing authorization of its version of the drug on the basis of: (1) the test data supplied by the originator of the test data; or (2) the marketing authorization previously granted; unless the originator of the test data consents. This test data protection continues for five years from the data of marketing authorization. In other words, where the Ministry of Health requires an innovator pharmaceutical producer to supply undisclosed test data on the safety and efficacy of a new drug, the Ministry of Health must protect that test data from disclosure for five years from the grant of marketing authorization. Consequently, if a generic pharmaceutical producer wishes to seek marketing authorization of its generic version of the same drug, the Ministry of Health cannot grant marketing authorization to the generic either first, using the innovator's test data, or second, referring simply to the previous marketing authorization (where, for example, the generic producer can demonstrate bioequivalence of the generic drug and the innovator drug).

The protection of test data covers test data relating to 'new' products. Article 15(10)(c) states that a 'new' pharmaceutical product is one which contains an entity that has not previously been granted marketing authorization in the country in question, namely Costa Rica. This is referred to as a 'national test'. A national test com-

pares to a 'global test' of newness. A global test considers those chemical entities that have not previously been granted marketing authorization anywhere in the world as 'new'. Thus, the national test considers a larger number of pharmaceutical products as 'new' in comparison to the global test, and as a result, affords protection to a broader range of test data.

Article 15(10)(b) adds an additional twist to test data protection. This article relates to the situation where a Party permits a third party to submit evidence concerning safety and efficacy of a pharmaceutical product previously approved in another country – this can be referred to as marketing authorization *by reference*. In such cases, the Party shall not permit a third person to obtain marketing authorization on the basis of evidence of prior marketing authorization or test data submitted for marketing authorization purposes in another country, for at least five years. Thus, for example, for a five year period from the date of marketing authorization in the US, the Ministry of Health in Costa Rica cannot grant marketing authorization to a generic producer of a drug by reference to either the prior marketing authorization granted to an innovator producer in the US, or alternatively, on the basis of the test data submitted by innovator producer as a condition for marketing authorization in the US.

The twist comes in the second half of Article 15(10)(b). The article goes on to say that, in order to receive protection under this article, a Party may require the person providing the test data in the other country to seek authorization in the Party's territory within five years of obtaining marketing authorization in the original country. Thus, for example, Costa Rica may require the innovator pharmaceutical company to seek marketing authorization for its pharmaceutical product in Costa Rica within five years of it being granted in the US, otherwise the innovator producer loses the possibility of test data protection. Importantly, where marketing authorization by reference is permitted, this potentially means that an innovator producer could receive 10 years test data protection – a five year grace period in which to seek marketing authorization in Costa Rica (during which time, the generic producer cannot rely on the test data or US marketing authorization for the generic drug), plus an additional five years of test data protection running from the date that the Ministry of Health in Costa Rica grants the marketing authorization for the innovator drug.

Article 15(10)(d) states that, where a Party discloses test data that has been provided for the purposes of marketing authorization, the Party must protect that test data from *unfair commercial use*. Thus, if the Ministry of Health discloses the test data, for example for reasons of public health, the party must nonetheless protect it from unfair commercial use. This is the first reference to 'unfair commercial use' in the article (apart from footnote 15 which is not relevant for present purposes). One interpretation would mean that the government, even though it had disclosed the test data, would have to treat the disclosed information as if it were undisclosed and confidential if a generic producer wished to rely on it for reasons of seeking marketing authorization of a generic drug.

In Costa Rica, Law 7975 'Ley de Información no Divulgada' protects undisclosed information related to commercial and industrial secrets that are confidential in nature

from use by third parties without consent, contrary to fair commercial use.[22] The article defines uses contrary to fair commercial use as practices in breach of contracts, abuses of confidentiality, and knowledgeable or negligent disclosure of undisclosed information by third parties. However, the Law does not protect information which is already in the public domain, which is required to be divulged by judicial order or can be obtained by reference to information already in the public domain. In accordance with the TRIPS Agreement, the Law protects test data provided on request from the Ministry of Health for purposes of obtaining marketing authorization for a pharmaceutical product and establishes that the Caja Costarricense de Seguridad Social (CCSS) can set conditions for use of that information by third parties.

Costa Rican law, prior to CAFTA, was in conformity with the TRIPS Agreement. To bring the law into conformity with CAFTA, the Parliament passed the Reforma, Adición y Derogación de Varias Normas Que Regulan Materias Relacionadas Con Propiedad Intelectual (Law 8686) on 21 November 2008.

Protection of test data supplied for marketing authorization purposes
Law 8686 protects undisclosed test data supplied for reasons of marketing authorization of a new pharmaceutical product against any unfair commercial use and from any disclosure, unless disclosure of the test data is necessary to protect the public.[23] In order to receive protection, the creator must have used considerable effort in creating the test data and the Government must have required the test data as part of the process of marketing authorization.[24] Protection is for five years from the first registration of the product in Costa Rica.

Definition of a 'new product'
Law 8686 defines a 'new product':

> 'new product is a product that does not contain a chemical entity that has been previously approved in Costa Rica'.[25]

The Regulations limit the definition of 'new products' so that '[n]ew uses or indications of existing products, changes in the administration or dosage, in pharmacological form or in the formulation of the chemical entity or those products constituting combinations of previously registered chemical entities already authorized in the country shall not be considered new products'. This can avoid extending test data

22 Article 2.
23 Law 8686, Article 6 reforming Article 8 of Law 7975, *Ley de Información No Divulgada*.
24 *Ibid*.
25 *Ibid.* (translations by the author).

protection beyond the five year period, for example avoiding test data protection for test data relating to a new use of an old product.[26]

Registration by reference to marketing authorization in a foreign country
Discussions with the CCSS and the Ministry of Health stated that the Ministry would not register pharmaceuticals by reference to decisions in foreign countries, such as those of the US Food and Drug Administration. Consequently, the possibility of a pharmaceutical producer gaining 10 years test data protection – being five years grace period to request registration and five years protection from the date of marketing authorization – will not be possible in Costa Rica.

Exceptions to protection of test data
In keeping with CAFTA, the Costa Rican legislation allows an exception to test data protection where disclosure is necessary to protect the public. Where undisclosed test data is disclosed in the public interest, measures must be taken to avoid unfair commercial use of the data.[27]

The Costa Rican implementing regulations had initially included several exceptions to test data protection, including one that withheld protection concerning data related to a pharmaceutical or phytosanitary product subject to a compulsory licence – Law 8632 of March 2008 in the Article on Public Interest Licences.[28] Nonetheless, in a somewhat surprising turnaround, Law 8686 of November 2008 deleted the article in order to comply with US demands. In other words, under the March 2008 Law, the Ministry of Health could have relied upon test data originally supplied by the patent holder to register and obtain marketing authorization of the patented pharmaceutical product in order to obtain the registration and marketing authorization of the pharmaceutical product produced under compulsory licence. The Ministry of Health would still have had to protect the test data against any unfair commercial use. Such a provision would have been important in ensuring that the pharmaceutical products produced under compulsory licence in the public interest could have been registered and authorized for marketing in a timely manner so as to take advantage as quickly as possible of the provision of affordable medicines. With the subsequent deletion of this article, the possibility of using test data to approve a pharmaceutical product produced under licence is left hanging. If test data cannot be used, this would effectively render the compulsory licencing option useless.

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26 Article 4, Reglamento a la Ley de Información No Divulgada, Nº 34927-J-COMEX-S-MAG, 26 November 2008, in Hernández-González, G., M. Valverde, and C. Murillo, *Evaluación del Impacto de las Disposiciones de ADPIC+ en el Mercado Institucional de Medicamntos de Costa Rica*, Centro Internacional de Política Económica (CINPE) y International Centre for Trade and Sustainable Development (ICTSD), December 2008, on file with the author.

27 Reform of Article 8 of Law 7975 (Undisclosed Information) of 4 January 2000, in Article 6, Law No. 8686. 'Reforma y adición de varias normas que regulan materias relacionadas con propiedad intelectual'.

28 Law 8632, Article 20.

Similarly, draft Regulations had originally stated that '[w]hen, at the date of presentation of the application for marketing authorization in Costa Rica, the pharmaceutical or phytosanitary product has had its approval of marketing authorization in a foreign country valid for more than six months', test data protection would no longer be available.[29] This would effectively have required the test data holder to seek marketing authorization in Costa Rica within six months of initial authorization permitting a total of 5.5 years protection. By not including this exception, the test data holder could effectively enjoy longer protection. For example, a test data holder could enjoy 10 years test data protection by applying for marketing authorization five years from the data of marketing authorization in the US – thus enjoying five years of protection prior to the application for marketing authorization in Costa Rica and an additional five years of protection after marketing authorization in Costa Rica. In this way, a generic producer could be obstructed from entering the Costa Rican market for ten years.

Table III.3 – Test data protection

TRIPS	**CAFTA**	**Costa Rican Legislation**
Protection of undisclosed test data in relation to new pharmaceutical products from unfair commercial use where marketing authority (MA) requires data for marketing authorization.	Protection of test data in relation to new pharmaceutical products for five years where MA requires the data.	Protection of test data for five years against unfair commercial use and against any disclosure. The MA must have required the test data for marketing authorization in order to gain protection
	Protection of test data where MA does not require data but relies on decision of a foreign MA.	Marketing authorization by reference to foreign MA not included in legislation.
Protection of test data against unfair commercial use.	Protection of test data not limited to unfair commercial use – effectively granting 'exclusive rights' over test data.[30]	Protection against unfair commercial use as well as against any disclosure – exclusive rights subject to public interest limitation

29 Reglamento de la Ley de Información No Divulgada, Anteproyecto de Decreto Ejecutivo, *La Gaceta* No. 228, Tuesday, 27 November 2007.

30 Correa, C., 'La protección de productos farmacéuticos y agroquímicos ('Productos Regulados') en DR-CAFTA', Puentes, VII(5), Octubre-Deciembre 2006, p. 11.

Global test – protection of test data relating only to 'new' pharmaceutical products – products not subject to marketing authorization anywhere in the world.	National test – protection of test data relating to pharmaceutical products not subject to marketing approval in the specific country ie Costa Rica (ie prior disclosure in the US not considered disclosure in Costa Rica).	National test included.
Producer of test data must expend 'considerable effort' in elaborating data in order to gain protection.	No such requirement.	Producer of test data must expend 'considerable effort' in elaborating the data to gain protection.
Exception to test data protection is possible in order to protect the public interest.	An exception to protection of test data is possible in order to protect the public interest.	Public interest exception included. Additional exceptions relating to compulsory licences and setting time limits to gain protection included in draft Regulations not included in final laws.
Protectrion of only undisclosed test data supplied for marketing authorization.	Protection of test data even where test data has been disclosed by the MA (eg for reasons of public interest) – ie test data treated as if it were undisclosed.	Protection of test data even where test data has been disclosed by the MA

Linkage

Article 15(10)(2) includes a provision on what has become known as 'linkage'. Linkage refers to requirements that the marketing authority in a country prevents a generic producer from marketing a patented pharmaceutical during the term of the patent. Where a country, such as Costa Rica, permits a generic producer to rely on test data already provided for purposes of marketing authorization, the marketing authority (the Ministry of Health), must implement measures in order to prevent marketing authorization occurring during the patent term. Further, the Ministry of Health has an obligation to inform the patent holder of the request and the identity of the generic producer making the request. The TRIPS Agreement does not include such a provision. Some commentators have claimed that this effectively makes the Ministry of Health the 'patent police'.[31] This raises questions of whether the Ministry of Health has the capacity and experience to undertake judgments regarding intellectual property.[32]

31 Macaya, R., *The Economic and Social Consequences of Overprotection of Intellectual Property Rights in CAFTA*, Briefing Paper, National Chamber of Generic Products, Cartago, Costa Rica, 2005, p. 2.

32 Macaya, *ibid.*, p. 2.

Law 8632 amends Article 16 of Law 6867 by adding a requirement that the Ministry of Health and other competent authorities must implement measures in the process of applying for marketing authorization of medicines in order to avoid any third persons from commercializing a patent protected product (without the consent of the patent owner). Article 24 of the Regulations to the Law[33] stipulates that to comply with the Law, the Ministry of Health should place on its web site a notification of applications for health registration, within 15 days of the application, so that the patent holder will be in a position to take legal action where necessary. Article 24 also stipulates that the Ministry must publish a list of pharmaceutical products granted health registration within 15 days of the emission of the health registry.

Table III.4 – Linkage provisions		
TRIPS	**CAFTA**	**Costa Rican Legislation**
No reference.	Marketing authority (MA) to prevent marketing authorization of generic during patent term.	Ministry of Health to implement measures to ensure that third parties do not market a pharmaceutical during patent term.
	MA to inform patent holder of any request for marketing authorization.	MoH to introduce web notification of applications for health registration within 15 days of application. MoH to publish a list of pharmaceutical products granted health registration within 15 days of emission of the registry

Exceptions

Article 15(9)(3) includes exceptions. In similar terms to the TRIPS Agreement, CAFTA states that the Government 'may provide limited exceptions to the exclusive rights conferred by a patent provided that the exceptions do not conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties'.

Article 15(9)(5) of CAFTA includes what is known as the Bolar Exception. The Bolar Exception permits the use of the subject matter of the subsisting patent to generate information necessary for marketing authorization of a drug. In such cases, the Government must ensure that any product produced using that information shall not be made, used or sold in that territory other than for purposes of meeting marketing authorization requirements in preparation for when the patent expires. If exportation is permitted, the Party must ensure that the product will only be exported for purposes

33 Regulations to the Law on Undisclosed Information (No. 34927-J-COMEX-S-MAG), 26 November 2008, in: Hernández-González, G., M. Valverde, and C. Murillo, *Evaluación del Impacto de las Disposiciones de ADPIC+ en el Mercado Institucional de Medicamntos de Costa Rica*, Centro Internacional de Política Económica (CINPE) y International Centre for Trade and Sustainable Development (ICTSD), December 2008, on file with the author.

of meeting marketing authorization requirements of that country. The Bolar Exception relates to use of the information disclosed as a result of the patent application – in other words, information in relation to the innovation itself and its reproduction – for purposes of getting marketing authorization, including in the creation of test data in order to apply for marketing authorization. However, the Bolar Exception does not allow a third party to refer to test data which is protected as undisclosed information.

In Costa Rica, Article 6 of the Draft Regulations mentioned above allows certain uses of test data which are otherwise protected. In relation to the Bolar Exception, a third party can rely on the information disclosed in the patent document or to rely on protected test data as evidence to support an application for registration and marketing authorization of a generic pharmaceutical drug; however, in such cases, the Ministry of Health must withhold the authorization to market the generic pharmaceutical product until after expiration of the patent protection or test data protection as relevant. Discussions with the Ministry of Health revealed that this is procedure that it will follow.

The same article in the Draft Regulations also allows the competent authorities to use undisclosed information, such as test data, without disclosing the protected information, with a view to preventing anti-consumer practices or to protect life, health or human security or the life or health of animals or vegetables or to protect the environment, with a view to preventing the abuse of intellectual property rights or recourse to unfair commercial practices. Discussions with the Ministry of Health and Ministry of External Trade identified that such exceptions are anticipated in the future regulations.

In conclusion, the TRIPS Agreement, CAFTA and the Costa Rican legislation are consistent in relation to exceptions.

Compulsory licences, parallel imports and the 'Understanding'

The United States had intended to use CAFTA as a means of restricting the use of compulsory licences and prohibiting parallel imports.[34] However, Chapter 15 of CAFTA does not place any additional explicit restrictions on compulsory licences or parallel importing beyond the TRIPS Agreement. It is important to underline two issues here. First, pharmaceutical products produced under compulsory licence or purchased through parallel importing are still subject to the same marketing authorization regime. The requirements in CAFTA to protect test data might therefore have an impact on the time it takes for products produced under compulsory licence or purchased through parallel importing to receive marketing authorization and enter the

34 Alonso, E., A. Castro, *Estado de la Nación en Desarollo Humano Sostenible: Aportes para el Análisis del Tratado del Libre Comercio Centroamerica, República Domincana, Estados Unidos,* Capítulo 15, Propiedad Intelectual, Consejo Nacional de Rectores, Defensoría de los Habitantes, Informe al 15 de diciembre del 2004, p. 23.

market. Consequently, CAFTA might indirectly affect compulsory licensing and parallel importing by delaying the marketing of those products.

Second, while Chapter 15 of CAFTA does not refer to compulsory licences, an Understanding in the form of a side letter to CAFTA does. The Understanding suggests that CAFTA's provisions are compatible with the Doha Declaration on the TRIPS Agreement and Public Health, including the right of the State to protect public health and to grant compulsory licences. In addition, the Understanding envisages consultations between the Parties to CAFTA in the event of an inconsistency arising. However, such Understandings are not an integral part of the agreement and only have interpretive value[35] and are vaguely worded.[36]

However, two potential areas of confusion arise as a result of this Understanding, albeit not particularly grave. First, as noted above, a pharmaceutical product produced under compulsory licence would still normally have to respect the protection of test data as set out under CAFTA. If a patent owner decides to challenge a generic producer seeking approval of a generic drug produced under compulsory licence on the basis that the approval process uses protected test data, the effect of the Understanding remains to be seen. The alternative would be that the generic producer producing under compulsory licence would have to produce its own test data which could ultimately have the effect of diminishing the public health protections in the Doha Declaration.

The second area of confusion is that the Understanding appears to narrow the accepted grounds for granting a compulsory licence. The TRIPS Agreement appears to allow the grant of compulsory licences so long as 'the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time'.[37] This requirement may be waived in cases of 'national emergency', 'other circumstances of extreme urgency' or 'in cases of public non-commercial use'. The Understanding on the other hand appears to address compulsory licences only in terms of 'national emergency' or 'extreme urgency'. However, this apparent narrowing of the use of compulsory licences should not be considered too seriously, given the ambiguous standing of the Understanding in comparison to the legal rights and obligations granted under the TRIPS Agreement.

In Costa Rica, the concession of a patent carries the obligation to exploit the patent in Costa Rica, permanently and stably.[38] To fulfil this requirement, the patent holder must supply the local market in a reasonable manner, either three years from the grant of the patent or four years from the patent application, whichever is the longer period. In the case where a patent has been granted but the patent holder has not yet received marketing authorization, the time period begins from the date of marketing authoriza-

35 Correa, C.M., 'Implications of Bilateral Free Trade Agreements on Access to Medicines', Public Health Reviews, *Bulletin of the World Health Organization*, 84(5), 2006, 399-404, p. 402.

36 Macaya, *op.cit.*, p. 5.

37 The TRIPS Agreement, Article 31(b).

38 Law 6867, Article 18.

tion.[39] Moreover, the patent holder should not interrupt the exploitation of the patent for more than a year. In the case of a failure to exploit the patent, a third party may apply for the grant of a compulsory licence. Further, compulsory licences may be granted where the patent holder has engaged in anti-competitive practices[40] or where such licences are required in the public interest, in the case of national emergencies, to protect national security and for reasons qualifying as extremely urgent.[41] As noted above, it is no longer clear whether the Ministry of Health will be able to rely on the test data supplied for the registration and marketing authorization of the original patented pharmaceutical product in order to register and authorize the product produced under compulsory licence, thus rendering the future of this option quite questionable.

Table III.5 – Compulsory licences		
TRIPS	**CAFTA**	**Costa Rican Legislation**
Compulsory licences (CL) permitted.	Compulsory licences permitted – 'Understanding' annexed appears to suggest compatibility between TRIPS and CAFTA in this area.	Compulsory licences permitted.
	Test data protection could diminish use of compulsory licences by delaying marketing authorization of pharmaceuticals produced under compulsory licence.	Test data protection could diminish use of compulsory licences by delaying marketing authorization.
CL may be granted including where a third party has attempted unsuccessfully to obtain authorization from patent holder on reasonable terms. This requirement can be waived in cases of 'national emergency', 'extreme urgency' or 'public non-commercial use'.	'Understanding' appears to narrow grounds for CL to only cases of 'national emergency' and 'extreme urgency'.	Compulsory licences may be granted where patent holder has engaged in 'anti-competitive practices', or where a CL is required in the 'public interest', in cases of 'national emergency', 'extreme urgency' or to protect 'national security'.

Enforcement provisions

Enforcement is relevant at two levels in relation to CAFTA and intellectual property rights. The first level concerns the inclusion of enforcement provisions within Chapter 15 itself. Chapter 15, Section 11, deals with 'Enforcement of Intellectual Property

39 Modificaciones al Reglamento de la Ley de Patentes de Invención, Dibujos, y Modelos Industriales y Modelos de Utilidad, Decreto No. 15222 MIEM-J-del 12 de diciembre de 1983, dated 18 September 2008, Article 2.

40 Law 6867, Article 19.

41 Law 6867, Article 20.

Rights'. Article 15(11)(1) states the understanding that the Parties implement the enforcement provisions in accordance with their own legal systems and principles of due process. Article 15(11)(6) requires each Party to make available civil and administrative remedies and procedures available to holders of intellectual property rights, such as patents or test data exclusivity and subsequent articles set out provisions relating to provisional measures of protection, remedies such as damages, and the award of costs. Article 15(11)(26) provides for criminal procedures and penalties at least in relation to willful trademark counterfeiting or copyright or related rights piracy on a commercial scale. The Article makes no mention of criminal procedures in relation to breach of patents or test data exclusivity, although the inclusion of the qualification 'at least' does suggest that criminal penalties could have a broader reach in practice.

In addition, Chapter 20 of CAFTA establishes mechanisms for the settlement of disputes, first concerning resolution of disputes between Parties in relation to the application or interpretation of the Agreement; and, second, in relation to domestic court proceedings relating to issues covered by CAFTA and promotion of alternative dispute resolution in relation to disputes concerning private parties. With regard to inter-state disputes, panels are established on an ad hoc basis, consisting of three experts chosen from a roster. Experts must meet certain basic criteria such as having expertise or experience in law, international trade or any matter covered by CAFTA, and they must be independent from the Parties. So long as the Parties to the dispute agree, the Panel may request information from experts – which technically could include human rights experts. The Panel normally drafts an initial and a final report on the basis of the relevant provisions in CAFTA, the submissions of the Parties and information requested from experts as previously mentioned. If the disputing Parties request, the Panel may make recommendations. The Parties then agree on a resolution of the dispute which is normally in accordance with the Panel's recommendations. In cases of non-compliance with a Panel report, Chapter 20 permits a Party to suspend benefits under CAFTA amounting to an equivalent loss.

In Costa Rica, Law 8039 of 12 October 2001, Ley de Procedimientos de Observanciea de los Derechos de Propiedad Intelectual, sets out civil and penal sanctions, including interim measures, in the event of abuse of intellectual property rights, including patents or protected undisclosed information such as test data. Decreto Legislativo No. 8656, Modificación de Varios Aríclos de la Ley de Procedimientos de Observancia de los Derechos de Propiedad Intelectual, and the Law 8686 mentioned above, ensure compliance with CAFTA. Additionally, intellectual property is protected under the Constitution. The Costa Rican Constitution prohibits monopolies and recognizes a right to some form of protection of intellectual property. Article 46 of the Constitution provides for a general prohibition on monopolies and recognizes freedom of commerce. Article 47 of the Constitution provides that every author, inventor, producer or business person shall temporarily enjoy exclusive rights over a work, invention, trade mark of trade name in accordance with the law. For present purposes, there is no need to go into further detail on the contents of these Laws.

Certification by the US prior to adoption of legislation and regulations

While not part of CAFTA itself, the US Congress passed the Dominican Republic-Central America-United States Free Trade Agreement Implementation Act in August 2005 which requires, as a condition for CAFTA to enter into force, a determination by the US President that the countries to the agreement, including Costa Rica, have taken measures necessary to comply with the provisions of CAFTA. This has become known as the certification process and has involved the Costa Rican Ministry of External Trade (COMEX) seeking US approval for the many and various implementation laws and regulations related to the Agreement.[42] While the certification process was not included in the original agreement, it was included in a subsequent amendment to Article 22(5), agreed to by Costa Rica and passed into legislation by the Costa Rican Parliament.[43]

4.3 Human rights and access to medicines in Costa Rica

Normative framework

The right to health and the right to life are the human rights most directly related to access to medicines, both of which Costa Rica has recognized at the international and national levels. As already mentioned, Costa Rica has ratified ICESCR and ICCPR and has therefore accepted legally binding obligations in relation to the right to health and right to life respectively. Costa Rica also allows individual communications in relation to the ICCPR and CEDAW, and was an active participant in the negotiations on an individual communications procedure in relation to ICESCR, suggesting a general recognition of the justiciability of the right to health and the right to life.

The Constitution recognizes the right to health and the right to life. Article 21 recognizes that human life is inviolable. Article 46 states that consumers and patients have a right to protection of their health, environment, security and economic interests and Article 73 establishes a system of social security consisting of contributions from the State, employees and employers, for workers to protect against risks relating to sickness, disability, maternity, old-age, death and other contingencies determined by

42 Dominican Republic-Central America-United States Free Trade Agreement Implementation Act, Public Law 109-53, 2 August 2005, section 101(b). Interestingly, section 102 of the same law states that: 'No provision of the [CAFTA] Agreement, nor the application of any such provision to any person or circumstance, which is inconsistent with any law of the United States shall have effect'. Consequently, while the countries of Central America and the Dominican Republic have had to undergo a substantial process of law reform in order to bring their legislation and regulations into conformity with CAFTA, the US has ensured that it need not undergo any such process of law reform, US law prevailing in any case.

43 Ley 8664 of 24 August 2008, Aprobación de Varioas Enmiendas al tratado de Libre Comercio República Dominicana-Centroamérica-Estados Unidos, aprobado por la ley 8622. The amendment to CAFTA requires the exchange of notes of certification between the signatory state and the US.

law. To this end, the Constitution established the Caja Costarricense de Seguro Social (CCSS). Costa Rican legislation also recognizes the right to health through the Ley General de Salud 1973 as well as the Ley 8239 Derechos y Deberes de las Personas Usuarios de los Servicios de Salud Públicos y Privados 2005. Article 20 of the General Health Law establishes that everyone has the right to access State health services while Article 21 states that everyone may receive medicines for the treatment of sickness and personal rehabilitation, in conformity with laws and regulations. Amongst other issues, Article 2 of the 2005 Law establishes a right to receive medical attention with appropriate efficiency and diligence, a right to receive, without distinction of any kind, treatment with respect, consideration and friendliness, and also a right to present complaints in case of violation of the right to health.

The Defensoría de los Habitantes has developed some general principles concerning public policy in relation to access to medicines and the right to health. These include the following: first, within the limits of available treatments, the treatment should cause the fewest adverse effects to the patient in comparison to treatment equivalents; second, the treatment should not only meet the needs of the patient but also the requirements of science and technology in confronting the specific illness; third, scientific uncertainty should not prejudice the right of the patient to the best treatment available; fourth, each patient has the right to receive from the Health System the best therapeutic alternative available which does not put the patient's health or quality of life at risk unnecessarily, nor the patient's right to life.[44]

The constitutional rights to life and to health are justiciable in Costa Rica. Individuals can bring a claim, seeking relief in the form of an *amparo* remedy – a constitutional proceeding intended to provide rapid relief with a view to protecting an individual's basic rights. The Constitutional Court hears a steady stream of such claims, many of which involve claims to protect the right to health through access to medicines. The *amparo* remedy has had a significant impact on ensuring access to medicines for Costa Ricans. A key case came in 1997 when William Garcia, a man seriously ill with AIDS, brought an application to the Constitutional Court for access to appropriate HIV treatments. Until that time, the CCSS had not supplied HIV treatments free of charge. However, the Court ruled in favour of Mr. Garcia which helped to ensure access to almost all HIV treatments through the CCSS free of charge. The *amparo* remedy has also been available to ensure access to other treatments, such as cancer treatments. Discussions with key informants during preparation of the case study indicate that the Caja Costarricense de Seguridad Social respects the decisions and the procedure provides a sure way of enforcing individuals' right to health and right to life.[45]

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44 Defensoría de los Habitantes de la República, *op.cit.*, p. 23.

45 For example: interviews with Albin Chavez, CCSS, Richard Stern, AIDS and human rights activist, Carlos Valerio, Defensoría de los Habitantes. A collection of a long list of decisions of the Constitutional Court concerning *amparo* remedies in relation to the right to life and the right to health, including cases on access to medicines, is on file with the author.

In addition to the *amparo* remedy, individuals may also bring a communication to the Defensoría de los Habitantes, the national human rights institution of Costa Rica. The use of this alternative is slower than the *amparo* remedy although its focus on mediation can help to identify the root of problems facing access to medicines and, potentially, provide more sustainable solutions. The Inter-American Human Rights system provides a further avenue to fulfil the right to health. Individuals have brought communications before the Inter-American Human Rights Commission which has ordered interim measures to provide patients with HIV treatments.[46] Discussions revealed that not all States respected the Commission's decisions to the same degree; however, the decisions provided a useful lobbying tool for activists to continue lobbying for universal access at the national level.[47] Experience at the level of the Inter-American Court of Human Rights is limited as the Court has considered few cases concerning economic, social and cultural rights generally, or specifically the right to health. The extent to which the Court might also provide an avenue for relief to ensure universal access to medicines therefore remains open.

Costa Rica's regime to provide universal access to essential medicines

Costa Rica's policy on selection and provision of essential medicines dates back to 1982.[48] The policy involves a detailed process of selection, acquisition, distribution and use of essential medicines provided by the Caja Costariccense de Seguridad Social (CCSS) financed through contributions from employers, employees and government. The private sector also provides access to medicines through a network of some 850 pharmacies across the country.

In terms of the selection process, the CCSS does not provide access to all existing medicines but rather relies on the WHO's Essential Drugs List to help guide its drug selection and balance public health needs with the capacity to provide drugs through the national health system. A Committee of 13 medical specialists from various hospitals in the country and technical specialists from the Department of Medicines and Therapy select the medicines on the *Lista Oficial de Medicaments* (LOM). The criteria for selection are drawn from the WHO and are: availability at any time; in sufficient amounts; in appropriate forms; with guarantees as to quality, harmlessness, sufficiency of information and a fair price. Once selected, the CCSS begins a process of acquisition and distribution and finally use of medicines.[49]

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46 See e.g., Jorge Odir Miranda Cortez *et al* v. El Salvador, Case 12.249, Report No. 29/01, OEA/Ser.L/V/II.111 Doc. 20 rev. at 284 (2000).

47 Discussions with Richard Stern, AIDS and human rights activist in Costa Rica, 26 November 2008.

48 *Política de los Medicamentos Esenciales de la Caja Costarricense de Seguridad Social*, Decreto Ejecutive 13878-SPPS of 22 September 1982, substituted by Decreto Ejecutivo 19343-S of 23 November 1989.

49 Caja Costariccense de Seguridad Social, *Medicamentos, Caja Costariccense de Seguridad Social y Mercado Nacional y Internacional*, (available at: http://www.comex.go.cr – accessed on 5 October 2008), p. 26.

The policy has enabled universal and free coverage and optimal access to essential medicines as well as relative stability in expenditure on medicines.[50] In 2006, the CCSS provided 627 pharmaceutical preparations and 453 active principles. The drugs provided by CCSS through the *Lista Oficial de Medicamentos* treat around 98 percent of the illnesses affecting the population. The Open Therapeutic Formula, also administered by the CCSS, provides treatments for the other two percent of illnesses which permits the acquisition of drugs not on the LOM but which are needed to treat special cases. According to the CCSS, this has ensured coverage at an optimal level that oscillates between 95 percent and 100 percent of the population.[51] A recent study by the Ministry of Health indicates that the CCSS is responsible for 43 percent of pharmaceutical purchases in Costa Rica, the rest being supplied through the private sector.[52] The CCSS guarantees access not only to citizens but also to residents, and in some cases to non-residents, such as assistance in emergency situations and for basic health care. This has helped to promote the rights of persons living in vulnerable or disadvantaged situations and to avoid discrimination.

Information received during the case study identified undocumented migrants as more vulnerable in the area of access to medicines.[53] As the most wealthy and stable Central American country, Costa Rica has attracted migrants from the region, particularly from Nicaragua, some of whom are undocumented. While undocumented migrants do have access to very basic medical attention, including, for example, vaccinations or in emergency situations, they do not have access to other medicines such as HIV treatments. Several reasons exist for this restriction: first, undocumented workers are often transitory which could lead to interruptions where treatments are continuous and ultimately health problems for the individual; second, as neighbouring countries do not provide the same level of access to medicines, there is a need to control access to avoid an influx of undocumented migrants seeking medical attention; third, there are fears that undocumented migrants might take medicines and sell them on in their own countries upon their return.[54] In some cases, the Defensoría de los Habitantes has helped undocumented migrants receive access to medicines where the individuals have been able to demonstrate a stable residence in the country – which, generally, has involved residency in religious hostels. A complicating factor for the right to health is that undocumented migrants sometimes avoid seeking medical attention even where it is available, for fear of being expulsed from the country.

Persons with HIV/AIDS are also vulnerable to the state of the access to medicines regime. While the CCSS does provide HIV treatments free of charge, access has not

50 CCSS, *ibid*., pp. 7ff.

51 CCSS, *ibid.*, p. 9.

52 Ministerio de Salud Pública e Instituto Nacional de Estadística y Censos de Costa Rica. (2008). *Primera encuesta de gastos de los hogares en salud*. San José in: Hernández-González et al, *op.cit.*, p. 3.

53 Discussions with Richard Stern, AIDS and Human Rights Activist in Costa Rica, 26 November 2008; Carlos Valerio, Defensoría de los Habitantes, 27 November 2008.

54 Discussions with Carlos Valerio, Defensoría de los Habitantes, 27 November 2008.

always been smooth, and the highest number of communications dealt with by the Defensoría de los Habitantes in the area of access to medicines concerns this group of persons, generally related to the quality of treatments provided by the CCSS (for example, where generics have not met quality standards) or where a particular HIV treatment has been momentarily unavailable due to lapses in supply.[55] Given that persons with HIV/AIDS are often subject to multiple-discrimination, for example, on the basis of health status and sexual orientation or as drug-users, this section of the population remains vulnerable to future changes in the access to medicines regime in Costa Rica.

Between 1995 and 2006, CCSS expenditure on drugs has been stable, maintaining a level of between a low of seven percent of the total CCSS budget in 2002 and a high of nine percent of the budget in 1998, 2000 and 2006. Of the total CCSS budget for pharmaceuticals, the amount spent on innovative drugs (drugs protected by intellectual property protection such as patents) represents approximately 30 percent, while around 70 percent of the budget goes towards purchase of generic drugs. The percentages do fluctuate from year to year within a relatively small margin. For example, in the years 2003, 2005 and 2006, the percentage of the budget spent on innovative drugs was 33 percent, 24 percent and 36 percent respectively. While Costa Rica has a relatively small pharmaceutical production, it is important to note that both innovator and generic pharmaceutical companies are represented in Costa Rica. Fedefarma, the Federación Centroamericana de Laboratorios Farmacéuticos, is the representative organization of innovator pharmaceutical producers in Central America, including Costa Rica.[56] ASIFAN, the Asociación de la Industria Farmacéutica Nacional, is the representative organization of the local generic pharmaceutical producers.

To date, the Caja has been able to maintain relative price stability concerning medicines on its official list. Two principal reasons explain this. First, the drugs on the LOM change gradually over time, with an average of 9 new active principles and pharmaceutical preparations entering the list a year and a relatively stable amount being taken off the LOM each year. Second, the time it takes for a patented drug to enter the LOM has meant that many generic producers are already producing generic versions of those drugs, which has had the effect of ensuring lower prices.[57] Importantly, the Caja provides these medicines on its LOM free of charge.

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55 *Ibid.*

56 Innovator companies with presences in Costa Rica are: Abbott Laboratories, Astra Zeneca, Bristol Myers Squibb, Eli Lilli, GlaxoSmithKline, Merck Sharp & Dohme, Pfizer, Roche. For more information on FedeFarma, see: http://fedefarma.org/index.php?option=com_content&task=view&id=17&Itemid=94 – accessed 18 November 2008.

57 Sources: Caja Costariccense de Seguridad Social, *op.cit.*; González Rodríguez, M., E. Chavarría Conejo y L.F. Guillén Picado, 'Segundo Curso Internacional: 'Derechos de Propiedad Intelectual y Salud Pública: Hacia un Régimen de Propiedad Intelectual que Proteja la Salud Pública y los Derechos de los Pacientes', Ministerio de Salud, Costa Rica (available at: http://www.iprsonline.org/ictsd/Dialogues/2007-05-27/Documents/Ministerio%20de%20Salud.ppt – accessed on 12 February 2009).

Enjoyment of the right to health in relation to access to medicines

On the current available information, it is possible to conclude that Costa Rica enjoys a relatively high respect for the right to health in relation to access to medicines. In keeping with the framework for the right to health developed by the Committee on Economic, Social and Cultural Rights:

- *Availability* – the Government provides a functioning public health system and health care facilities, goods and services, in keeping and potentially above, its level of development, including essential medicines.
- *Accessibility* – the Government ensures accessibility of medicines: the law protects against discrimination in access to medicines and access to remedies exist where this occurs; access to medicines is guaranteed across the country; essential medicines according to the CCSS official list are free.
- *Acceptability* – no evidence was found to suggest that the CCSS did not respect medical ethics or provide medicines that were culturally appropriate. It should be noted that recourse to the Constitutional Court and the Defensoría de los Habitantes provides a means of protecting against unethical or culturally inappropriate action, where problems occur.[58]
- *Quality* – the CCSS seeks to provide quality innovative or generic medicines and this is one of the purchasing criteria. Discussions with the Defensoría revealed that some problems exist regarding quality, although recourse to the Defensoría has helped to limit quality problems.

In relation to the State obligations towards the right to health in the area of access to medicines, the following preliminary conclusions are possible:

- *The obligation to respect* – the Government appears generally to respect the right to health and access to medicines. The Government does however restrict access to undocumented migrants, unless exceptional circumstances exist, such as demonstrated stability similar to residency. However, reasons appear to justify this restriction, at least in some cases.
- *The obligation to protect* – while the Government provides universal access to its list of essential medicines, the option of reliance on private provision exists. The Ley General de Salud ensures regulation of the private sector.[59]
- *The obligation to fulfil* – the Government has recognized the right to health in its legal system and provides remedies in the case of violations. It has adopted a

58 Discussions with Richard Stern, AIDS and Human Rights Activist, revealed that prior to the Constitutional Court's decision that led to provision of HIV treatments, a high-level representative of the CCSS had stated that the CCSS did not have resources to provide HIV treatments when the people with the virus were in the situation due to their own actions: 27 November 2008.

59 See e.g. Articles 71, 84 and 88.

national plan for access to medicines and supplies universal coverage of the population through a public insurance scheme.

4.4 Identification of potential impacts

Introduction

The question now arises as to the extent to which the TRIPS plus provisions of CAFTA will affect the relatively high level of enjoyment of the access to medicines and human rights in Costa Rica, either positively or negatively. This next element of the 'scoping' stage identifies the potential impacts of CAFTA to be subject to assessment in the 'analysis' stage. In order to identify potential impacts, this part of the 'scoping' stage relies on the ten impact categories developed in Chapter II as part of the methodology. While the methodology identifies ten impact categories, not all of them are necessarily relevant. On the basis of the secondary sources relied upon in the 'screening' stage, there is no specific claim that intellectual property protection will contribute to Costa Rican economic growth and the progressive realization of human rights (category two), nor that intellectual property protection will lead to a race-to-the-bottom in human rights standards (category five), limit the use of trade measures to improve human rights abroad (category six), nor that intellectual property provisions in CAFTA lead to normative conflicts with human rights standards (category seven). This leaves the remaining six impact categories. The six categories of 'impacts' are as follows:

Hypothesis one: CAFTA complements human rights
The patent and test data protection in CAFTA (the TRIPS plus provisions) might potentially have the effect of promoting human rights in two ways:

1. The TRIPS plus provisions might strengthen the right to the protection of the moral and material interests of authors and inventors, including through the provision of a right to a 2.remedy in the case of a breach;
2. The TRIPS plus provisions might promote medical research in Costa Rica and have a positive impact on the right to health;

Hypothesis two: CAFTA affects the capacity of the Government to fulfil the right to health
The TRIPS plus provisions of CAFTA could place additional strain on the CCSS either to increase its spending on access to medicines – potentially at the expense of other health services – or in reducing the quality of medicines supplied.

Hypothesis three: CAFTA breaches the right to health of Costa Ricans
The strain on CCSS capacity to fulfil the right to health might lead to the provision of medicines of lower quality or a reduction in public provision of medicines, leading to

a regression in enjoyment of the right to health and potentially a two-tiered system favouring wealthier patients who can access private insurance and purchase medicines privately.

Hypothesis four: Enforcement of CAFTA is stronger than for human rights treaties and threatens to prioritize trade agreements over human rights
The TRIPS plus provisions in CAFTA promote strong enforcement provisions for breach of intellectual property protection at both the national and international level, which could skew judicial and quasi-judicial enforcement in favour of the interests of holders of intellectual property such as pharmaceutical producers and away from the human rights of individuals and groups.

Hypothesis five: The processes of negotiation, adoption and implementation related to CAFTA have failed to and continue to fail to respect the right to take part in the conduct of public affairs
'Impact nine' examines the extent to which the implementation of the TRIPS plus provisions of CAFTA has respected, and is likely to continue respecting, the right to take part in the conduct of public affairs.

Hypothesis six: CAFTA's 'values' threaten human rights 'values'
The TRIPS plus provisions promote commercial interests of brand pharmaceutical companies over the interest of promoting national solidarity and human rights.

4.5 Assessment techniques

The Analysis section relies on four assessment techniques as follows:

1. *Economic modelling* – the HRIA relies on the results of a partial equilibrium model of the future impacts of CAFTA on access to medicines undertaken by Centro Internacional de Política Economica para el Desarollo Sostenible and the International Centre for Trade and Sustainable Development.[60]
2. *Causal-chain analysis* – in addition, the HRIA relies on causal-chain analysis using secondary materials to identify the likely cause-effect links between the introduction of the changes in intellectual property protection and the enjoyment of the right to access medicines.
3. *Expert judgment* – I rely on secondary materials (governmental, non-governmental and industry sources) and interviews in Costa Rica with key informants from government (Ministry of External Trade, Ministry of Health, CCSS, Patent Office),

60 Hernández-González, G., M. Valverde, and C. Murillo, *Evaluación del Impacto de las Disposiciones de ADPIC+ en el Mercado Institucional de Medicamntos de Costa Rica*, Centro Internacional de Política Económica (CINPE) y International Centre for Trade and Sustainable Development (ICTSD), December 2008, on file with the author.

industry (representatives of generic and brand pharmaceutical industry), the national human rights institution, academics and civil society organizations, as well as personal legal knowledge, to justify reasoning, as objectively as possible, on likely impacts of CAFTA on human rights and access to medicines.[61]

The HRIA relies on these three assessment techniques on the basis of the following (drawn from the Methodology in Chapter II).

a) *The stage of assessment* – the HRIA is an *ex ante* assessment undertaken at the early implementation stage where the Legislative Assembly has adopted most of the laws and regulations and CAFTA is about to enter into force for Costa Rica. Moreover, the assessment comes towards the end of a long period of public debate, a national referendum on the issue, and publication of a considerable amount of secondary materials. The existence of implementing laws makes legal analysis easier, while the existence of a wide variety of secondary materials helps substantiate analysis of existing materials, so long as the reliability and validity of the secondary materials is born in mind.
b) *The trade measure* – intellectual property protection potentially has economic impacts: the prices of essential medicines, the availability of generics. Consequently, reliance on the partial equilibrium model helps to predict the more likely economic impacts which can then be analyzed using a human rights framework.
c) *The human rights impact* – the human rights impact concentrates on the right to health specifically, although also authors' rights and the right to take part in the conduct of public affairs. The relatively strong human rights culture in Costa Rica, including the availability of jurisprudence, legislation and reports of the national human rights institution on the issue provides a considerable amount of secondary human rights material upon which to base the human rights analysis.
d) *The strength and weaknesses of the technique* – each of the three techniques has its weaknesses. First, economic modelling is as strong as the assumptions underlying the model and, while helpful in predicting future economic impacts, is not so helpful in going the next step in assessing impact on human rights. The use of analysis of legislation, jurisprudence and secondary materials as well as the use of key informants, helps to compensate for the weaknesses of the economic model;

61 Key informants were: Susana Vázquez (Ministry of External Trade); a former representative of Fedefarma (Federación Centroamericana de Laboratorios Farmacéuticos); Mario Devandas (independent expert); Karen Quesada (Registro Nacional); Albin Chaves (Caja Costarricense de Seguridad Social); Gabriela Arguedas (Parliamentary Councilor); Gilda Pacheco and Lorena Gonzalez (Inter-American Institute for Human Rights); Greivin Hernandez (one of the authors of the Partial Equilibrium Model study); Marcela Gonzàlez and Dra. Rodríguez (Ministry of Health); Alvaro Camacho (ASIFAN – National Association for Generic Pharmaceutical Companies); Richard Stern (Human Rights Activist); Oscar Parra (Inter-American Court of Human Rights); Roman Macaya (independent expert); Carlos Valerio (Defensoría de los Habitantes); José Maria Villalta (Parliamentary Councilor); Adrián Jiménez Ardón (Ministry of Migration).

however, the qualitative nature of much of this information places considerable pressure on the assessor to ensure clear reasoning and justification for conclusions.

e) *Data availability* – Costa Rica has a relatively developed system of data collection on intellectual property protection, access to medicines as well as human rights and the considerable amount of debate on CAFTA has resulted in a wide variety of data available. This has helped to strengthen the economic model and has provided a significant number of secondary materials upon which to base the analysis.
f) *Time and resources* – to undertake a full HRIA, considerably more time and more resources would be necessary. The use of key informants has also helped to economize the use of time. While in-depth interviewing or the use of surveys to assess current enjoyment of human rights in the context of access to medicines might also have been helpful, key informants provided a means of including representatives of duty-bearers and rights-holders, taking into account limitations of time and resources.
g) *Skills and capacity* – a team of assessors with a range of skills including economics, trade, law, health care and social science should normally be present in the assessment team. Such skills have not been available to undertake this HRIA, making reliance on secondary resources and legal analysis and the use of the results of an existing economic model appropriate.

4.6 Human rights indicators

Chapter II established the means of choosing relevant and valid human rights indicators to measure the impact of trade agreements on human rights. Tables III.6, III.7 and III.9 (towards the end of Chapter III) set out some basic indicators to assist in clarifying the likely impact of the TRIPS plus provisions of CAFTA on access to medicines and human rights. Each table is inter-related:

1. Table III.6 sets out the *general description* of indicators. These are indicators which, on the basis of a review of secondary materials and human rights norms related to access to medicines, should be able to help identify future changes in access to medicines as a result of the introduction and implementation of the TRIPS plus provisions.
2. Table III.7 sets out the *baseline situation* in relation to those indicators.
3. Table III.9, which appears at the end of the section on 'analysis', sets out the potential changes to those indicators as a result of the implementation of CAFTA.

Each table includes the same list of indicators in the same order.

Looking at Table III.6, the *first row* of the table sets out the 'attributes' of the indicators. The attribute is drawn from Article 12(2)(c) of the International Covenant on Economic, Social and Cultural Rights which requires States parties to take steps to achieve the full realization of the right to the highest level of physical and mental health including steps necessary for 'the prevention, treatment and control of epidemic,

endemic, occupational and other diseases'. This article has been chosen on the basis of it being the obligation in the Covenant most directly related to access to medicines. The *left hand column* sets out the three categories of indicators, namely structural, process and outcome indicators as explained in Chapter II. By considering the information in the previous sections of Chapter III and the human rights norms and standards relating to access to medicines, Table III.6 identifies relevant 'structural', 'process' and 'outcome' indicators. Table III.6 provides a narrative description of each indicator.

After the description of each indicator, the indicator is given a symbol comprising a letter 'S', 'P' or 'O', corresponding to the category of indicator (ie 'structural', 'process' or 'outcome'), as well as a number corresponding to the chronological order of the indicators in each category. Consequently, the first structural indicator is given the symbol 'S1'. Each table, namely Table III.6, Table III.7 and Table III.9, uses the same symbols to allow cross-referencing.

Consequently, the three tables should be read together. Consider the following example:

1. Table III.6, indicator 'S1' gives the generic description of the indicator as 'International human rights treaties, relevant to the right to enjoyment of the highest attainable standard of physical and mental health ratified by the State';
2. Table III.7 provides the baseline indicator in the context of Costa Rica today, namely: 'All core human rights treaties ratified except for the Migrant Workers Convention, the Disappearances Convention and the CRPD'.
3. Table III.9, which appears after the analysis stage, provides the result of the indicator in light of the introduction of the TRIPS plus provisions. Indicator 'S1' is in fact 'unchanged'. This is not surprising as, unless CAFTA required changes to human rights legislation such as the ratification of new human rights treaties, then it is unlikely that this indicator would change. This is not to say that the TRIPS plus provisions have no impact on the right to health, as structural indicators are helpful in understanding the effect of process indicators (in the row below) and how these might affect outcome indicators (in the bottom row).

It is important to highlight that the three tables do not include every indicator referred to in the HRIA. Indeed, much of the discussion refers to a range of quantitative and qualitative indicators without referring to them as indicators. This is particularly so in relation to process indicators as there are a range of economic and social factors that combine to influence the impact that intellectual property protection might have on access to medicines. However, the tables do provide sufficient data to establish both the baseline situation in Costa Rica related to access to medicines and human rights as well as to illustrate the potential impact of CAFTA in the future.

Table III.6 – Human rights indicators	
	Right to health – Article 12(2)(c) ICESCR – the prevention treatment and control of diseases
Structural	– International human rights treaties, relevant to the right to enjoyment of the highest attainable standard of physical and mental health (right to health), ratified by the State (S1) – Date of entry into force and coverage of the right to health in the Constitution or other forms of superior law (S2) – Date of entry into force and coverage of domestic laws for implementing the right to health (S3) – Time frame and coverage of national policy on access to medicines (S4) – Legal protections against discrimination (S5) – Number of active civil society organizations involved in the promotion and protection of the right to health in the context of CAFTA (S6) – Existence of structures for the use of parallel importing of essential medicines and compulsory licencing of essential medicines (S7) – Existence of grievance mechanisms in relation to the right to health and access to medicines (S8) – ICC rating of the National Human Rights Institution (S9)
Process	– Proportion of received complaints on the right to health investigated and adjudicated by the courts, national human rights institution, human rights ombudsperson, or other mechanisms, and the proportion of these responded to effectively by the government (P1) – Per capita government expenditure on access to essential medicines (P2) – Proportion of CCSS budget devoted to provision of essential medicines (P3) – Proportion of people covered by health insurance (break down public/private insurance) (P4) – Share of public expenditure on essential medicines in relation to private expenditure (P5) – Availability of additional funds to increase the CCSS budget (define the source) (P6) – Proportion of CCSS budget spent on medicines from innovator pharmaceutical companies (P7) – Proportion of essential medicines sourced through the compulsory licencing mechanism to ensure affordability (P8) – Identification of individuals who are vulnerable to changes in the access to medicines regime (P9)
Outcome	– Incidence of persons foregoing essential medicines (O1)

Table III.7 – Human rights indicators with data	
	Right to health – Article 12(2)(c) ICESCR – the prevention treatment and control of diseases
Structural	– All core human rights treaties ratified except for the Migrant Workers Convention, Disappearances Convention and the CRDP (signed not ratified). (S1) – Constitutional guarantees related to the right to health and other human rights dating from 1948. (S2) – Legislation and regulations relating to the right to health dating from 1973 and 2005. (S3) – The Official Medicines List is based on the WHO Essential Medicines List and revised annually by an expert committee. (S4) – The Constitution (Article 33) protects against discrimination and recognizes equality of all persons before the law; international treaties, including those protecting against discrimination, have constitutional hierarchy upon ratification. (S5)A precise figure was not available. Generally speaking, Costa Rica has an active civil society. (S6) – Legislation allows compulsory licencing on several grounds, including to protect the public interest, in national emergencies and extreme urgency, although no compulsory licence has ever been awarded; the CCSS relies on parallel importing in practice. (S7) – Costa Ricans can seek the *amparo* remedy in order to protect the right to access to medicines. (S8) – The Defensoría de los Habitantes, the Costa Rican national human rights institution, enjoys an 'A' rating from the ICC. (S9)
Process	– Precise figures were unavailable; however in spite of recent delays in the Constitutional Courts handling of applications for the *amparo* remedy, the process is generally quick and the government fully complies with decisions. (P1) – In 2006, the CCSS spent USD 84 million on pharmaceuticals, representing USD 22 per capita expenditure in a country of 4 million. (P2) – On average, 7 to 9 percent of the CCSS budget is spent on purchasing medicines. (P3) – Public health insurance covers 100 percent of the population, although limitations on undocumented migrants in relation to non-emergency treatments. Private health insurance is optional although no information on coverage was available. (P4) – Data was not available. However, over 800 private pharmacies provide private access to medicines indicating significant reliance on private provision of medicines as well. Further CCSS is responsible for 43 percent of pharmaceutical purchases. (P5) – Information was not available – however the medicines budget is only a proportion of the CCSS budget and the proportion fluctuates from year to year indicating a level of flexibility in CCSS budgeting to compensate for annual price changes. (P6) – 30 percent of CCSS medicine budget go to purchasing of innovative drugs. (P7) – No compulsory licences have been granted in Costa Rica to date. (P8) – Undocumented migrant workers are the most vulnerable. People unable to access private health insurance, particularly those living in poverty, would be vulnerable to changes to the access to medicines regime. (P9)
Outcome	– On information available, the incidence of people foregoing access to essential medicines is between 0-5 percent. (O1)

5. STEP FOUR: ANALYSIS

5.1 Introduction

The analysis section assesses the likelihood of each of the potential impacts identified in the 'scoping' section. The analysis has three steps. First, it begins by examining the direct impacts of the TRIPS plus provisions in CAFTA on extending what is termed 'market exclusivity'. Market exclusivity refers to the period during which a holder of intellectual property can exclude competitors from the market place. This is typically the effect of patent rights – in other words, the grant of patents provides the patent holder with a right, limited in time, to exclude competitors from certain acts such as selling the patented product. Test data protection also has the effect of excluding competition in practice as a competitor cannot gain marketing authorization to compete with brand pharmaceuticals without either access to that data, unless of course the competitor goes to the trouble of creating new test data. Second, relying on the results of the Partial Equilibrium Model, it predicts the effects of extended market exclusivity on prices for pharmaceuticals. Third, it interprets these results in terms of their impacts on human rights. It is important at the outset to make the distinction between the impact of the TRIPS Agreement and the impact of CAFTA. The TRIPS Agreement in fact is likely to have a far greater impact on issues such as access to medicines, given for example, the introduction of twenty year protection for patents over pharmaceutical products, as opposed to the previous one year level of protection enjoyed in Costa Rica. CAFTA has the potential to extend intellectual property protection and therefore accentuate those impacts, but to a more limited extent. It is therefore important to stress that the present assessment is only of the impact of the TRIPS plus provisions in CAFTA, and not of the impact of intellectual property protection of pharmaceutical products generally on human rights.

5.2 Step one: Impacts of CAFTA on extending market exclusivity of IP protected pharmaceuticals

The first step is to assess the direct impact of the various TRIPS plus provisions - patent restoration, test data protection and linkage – on extending the market exclusivity period for branded pharmaceuticals.

Patent restoration

The direct impact of the provisions on patent restoration depends on the extent to which the Registro Nacional (which houses the Costa Rican Patent Office) and the Ministry of Health (which grants marketing authorization to pharmaceuticals) can avoid administrative delays in the grant and examination of patents and the grant of marketing authorization for new pharmaceutical products. A second factor influencing the impact of patent restoration is the way in which the Costa Rican implementing

legislation defines the length of time for patent restoration when delays do in fact occur. Where significant administrative delays occur and patent life is extended, the result could be to delay entry of generic pharmaceuticals and thus to extend exclusive pharmaceutical pricing for a limited period.

Delays in the examination and grant of patents have been a problem in the past, although discussions with the Patent Office suggest that this is improving. One national expert, Roman Macaya, reports that there is currently a bottleneck in patent applications at the Public Registrar. Macaya notes that of 595 patent applications to the Public Registrar in 2006, only seven were granted that year.[62] Macaya further notes the increasing pressure on the Patent Office due to the progressive increase in general patent applications, rising from 76 in 2000, to 242 in 2002, 321 in 2004 and 595 in 2006 as noted above. PhRMA, the US innovator pharmaceutical lobby group, also notes significant delays in the processing of patent applications, recording 1,700 filings for patent and utility model protection from 2004 to 2006 but only 34 patents being granted.[63] Assuming that pressure on the Public Registrar continues, delays in the grant of patents over pharmaceutical products in the future could become more likely, triggering the patent restoration provisions of CAFTA, particularly given that, according to discussions with the Patent Office, some 60 percent of patent applications concern pharmaceutical products.[64]

The Patent Office does admit a bottle neck in patent applications but also notes that they are receiving an increase in resources, in the form of two additional examiners, and are benefiting from the use of new databases and cooperation with patent offices in other countries. The representatives of the Patent Office were confident that the bottleneck would be dealt with and that administrative delays in the examination and grant of patents would soon be kept to a minimum. The representative noted that while in 2005 and 2006 only 9 and 11 patents were examined, the figure jumped to 50 from May to October 2008, reflecting improved technology and staffing situation.[65] However, the representative admitted that there is still a significant backlog of applications.

In relation to administrative delays in the grant of marketing authorization, the Ministry of Health stridently claimed that it took an average of merely six months to consider applications, a far cry from the three year limit that defines a delay in marketing authorization in the implementing legislation. The representatives of the Ministry were confident that administrative delays were not a problem, neither now nor in the future.[66] However, it is relevant to note that the innovator pharmaceutical industry has

62 While this does indeed suggest the existence of a bottleneck, it could also suggest that many patent applications were simply not successful. Macaya R., *El TLC, las medicinas y los argumentos utilizados* (available at: http://www.anep.co.or.cr – accessed 12 February 2009).

63 See: 'Special 301 Submission 2008', Pharmaceutical Research and Manufacturers of America (PhRMA), (available at: http://www.ustr.gov – accessed 20 January 2008), p. 145.

64 Interview with Karen Quesada, representative of the Registro Nacional, 7 November 2008.

65 *Ibid*.

66 Discussions with Marcela González and Dra Rodriguez, Ministry of Health, 13 November 2008.

complained that the registration process in Costa Rica is one of the most bureaucratic in Central America, which in the past had led to delays in marketing new pharmaceuticals.[67] Nonetheless, the industry did not provide information on the extent of those delays.

On the information available, it appears that claims for patent restoration might arise in the future due to administrative delays at the Patent Office, but that they will be unlikely due to delays in the grant of marketing authorization, particularly given the confidence expressed by the Health Ministry that authorization takes only six months (which is well below three years). The implementing legislation has managed to limit patent restoration to 1.5 years and ensure that there can be no accumulation of patent restoration where delays occur in both the procedures of marketing authorization and the examination and grant of patents. Moreover, the request for patent restoration must be made significantly in advance of the restoration occurring, namely within six months of the eventual patent grant or marketing authorization, and patent restoration is excluded where there is more than 12 years left of the patent life at the time of granting marketing authorization.

In summary, patent restoration will be likely to have some, although decreasing, impact on extending the life of patents. This is due to: (1) the extent of stress currently on the Patent Office which is not likely to disappear in the near future; (2) the investment in infrastructure in the Patent Office which will improve the situation over the longer term; and, (3) the limitation of patent restoration to only 1.5 years no matter how long the delay. On the information available, it is unlikely that delays in marketing authorization would be sufficient to warrant patent extension.

Protection of test data

At the time of drafting the assessment, the relevant regulations on test data protection were not public. This adds an additional element of complexity to predicting the impact of test data protection, given the range of possible scenarios. A further layer of complexity is added due to the fact that the impact of test data protection will differ case-by-case, making it difficult to predict any magnitude of likely impact with any clarity. In general terms, the protection of test data could provide a means of stalling competition from generic competition – extending market exclusivity – in two ways:

– First, where the protection of test data extends beyond the life of the patent, for example, where the pharmaceutical producer sought marketing authorization in Costa Rica late in the life of the patent; or,
– Second, where the pharmaceutical owner decided not to apply for patent protection in Costa Rica but instead sought to exclude generic competition through reliance on five year test data protection. This opens up the possibility of gaining market

67 PhRMA, *op.cit.*, pp. 145f.

exclusivity over a pharmaceutical which is not sufficiently novel to receive patent protection or alternatively not worth the cost of seeking patent protection in Costa Rica.

It is important to highlight that the protection of test data would in many cases coincide with the patent protection term, during which time the patent holder already enjoys market exclusivity. If that were the case, the patent protection might already have the effect of excluding generic competition and test data protection would have no real impact.[68]

However, one area where test data protection could have a significant impact is in the award of compulsory licences. As noted in the 'Scoping' section, Law 8686 repealed the exception that would have allowed the use of protected test data for the purpose of marketing authorization of pharmaceuticals produced under compulsory licence. This could effectively deny any practical use for the compulsory licence mechanism given that a patent holder could use test data protection to delay entry of the competition by several years.

Linkage

The 'linkage' provisions of CAFTA provide innovator pharmaceutical producers with an early warning system to help delay competition from generics. In the absence of 'linkage' provisions, the Ministry of Health could potentially grant marketing authorization for a generic pharmaceutical and the patent owner might only be able to defend its patent rights once the generic is on the market – in other words, the brand pharmaceutical would not enjoy market exclusivity any longer but could seek damages or a revocation of marketing authorization. With the 'linkage' provisions, the patent owner has early warning of generic competition and could therefore delay generic entry by commencing proceedings prior to marketing authorization of the generic – thus, continuing the period of market exclusivity already granted by the patent. On the face of it, 'linkage' would not appear to extend market exclusivity as such, but rather maintain existing market exclusivity rights. However, the twist comes in the fact that, in the US at least, a high number of patents are in fact overturned in the process of litigation following early application of generics for marketing authorization.[69] Thus, a patent owner can enjoy market exclusivity over a pharmaceutical that does not meet the requirements of a patent for the period of the litigation. In the US, the Food and

68 As noted in the previous section, the process of patent application and market authorization takes around 8 to 12 years, sometime after which the process of patent application and market authorization in Costa Rica would finish. At least in some cases, test data protection could feasibly terminate between 9 to 17 years, and therefore prior to the termination of the patent application, leaving time for market authorization of the generic drug in time for the innovator drug to come off patent.

69 In the US, Macaya notes that some 46 percent of patents are revoked in such cases. Macaya R., 'El TLC, las medicinas y los argumentos utilizados' , *op.cit.*, p. 3.

Drug Administration takes an average of two years to resolve such disputes. The result is an extension of market exclusivity for innovator pharmaceuticals in some cases.

Three factors influence the impact of the 'linkage' provisions on extending the period of market exclusivity. First, the extent to which the Government has the capacity to cope administratively with the notification requirements and with the resolution of any disputes between innovator and generic companies could affect the period of time in which market exclusivity continues. Current drafts of the regulations suggest that the Ministry of Health will comply with the 'linkage' provisions through providing information to the public on marketing authorization applications on the Ministry's website. This would be a relatively simple procedure which would then allow a patent holder to defend its patent rights before the appropriate tribunal by challenging the marketing authorization application. Further, discussions with the Ministry of Health suggest that any disputes arising from the situation – for example the commencement of proceedings by the generic producer to revoke the patent – would be dealt with by the appropriate tribunal and not by the Ministry of Health.[70] Consequently, the 'linkage' provisions should not prove to be administratively burdensome for the Ministry of Health. However, it is assumed that the appropriate tribunal dealing with patent disputes in Costa Rica will have neither the experience nor the resources of the US Food and Drug Administration, thus extending the period of litigation – and market exclusivity – beyond two years.[71] This could have the effect of delaying entry of a generic pharmaceutical which, in the absence of the 'linkage' provisions, might already have received marketing authorization and be on the market.

The second factor influencing the extent of impact of 'linkage' provisions is the strategy employed by generic and innovator companies in challenging and protecting brand pharmaceuticals. In other words, the extent to which generic manufacturers are aggressive in seeking marketing authorization in relation to pharmaceuticals still under patent could reduce the impact of 'linkage' on maintaining market exclusivity. On the other hand, the extent to which innovator companies defend patents and challenge incoming generic competition could have the impact of extending market exclusivity. The third factor influencing the extent of impact of 'linkage' concerns the attitude of the Government, in particular in its dealings with abusive practices by innovator pharmaceutical companies. Discussions during the case study revealed the example of legislation in Australia which introduced stiff penalties for pharmaceutical companies using legislation to pursue anti-competitive practices such as defending bad patents aggressively.[72] The use of parallel importing and compulsory licencing by the

70 Discussions with Marcela Gonzalez and Dra Rodriguez, Ministry of Health, 13 November 2008.

71 This assumption is made on the basis of the fact that Costa Rica is a developing country and does not have the resources available to fund the administration of justice to the same extent as the US. Further, as 'linkage' is new in Costa Rica, it is also assumed that the relevant tribunal will not have the experience accumulated already by the US Food and Drug Administration in this area.

72 Discussions with Greivin Hernandez-González, CINPE, 13 November 2008.

Government could also have an impact on the extent to which 'linkage' provisions delay generic competition and extend market exclusivity.

In summary, it is likely that the 'linkage' provisions will extend the period of market exclusivity for brand pharmaceuticals beyond current levels, providing an early warning system for innovator pharmaceutical companies enabling them to delay entry of generic competition is introduced.[73] The extent of the impact will depend on: first, the capacity of the Government to deal with the administrative burdens of the notification scheme (which are minimal) and related litigation (which could be substantial); and second, the extent to which generic and innovator companies rely on aggressive tactics in challenging and protecting patented pharmaceuticals.

Preliminary conclusion on direct impacts on market exclusivity

In summary, all three TRIPS plus provisions are likely to have the effect of extending the period of market exclusivity enjoyed by brand pharmaceutical producers. This might not always be the case, but it is expected that it will be in at least some cases. The significance of this impact will depend on four inter-related factors:

1. The legal framework adopted by Costa Rica to implement CAFTA. On information currently available, it appears that the Government has sought to limit the extension of market exclusivity (for example, 1.5 years for patent restoration).
2. The capacity of the Patent Office, the Ministry of Health and relevant tribunals to meet the requirements in CAFTA (such as timely administrative procedures and meeting notification requirements).
3. The comportment of the market, namely the extent to which generic companies and innovator companies pursue their goals aggressively.
4. The extent to which the Government reacts to anti-competitive practices of innovator companies, for example, by relying on flexibilities in CAFTA such as compulsory licencing and parallel importing or punishing anti-competitive practices.

5.3 Step two: Impact of extended market exclusivity on prices

Accepting that CAFTA will have the effect of extending market exclusivity in relation to brand pharmaceuticals, the next question relates to the impact this will have on prices. Macaya provides a specific illustration of the difference in price between drugs offered under exclusivity and under competition as an indication of the potential impact of extended market exclusivity on prices. He demonstrates the impact that test data protection might have had on the price of neflinivar, a drug used to treat HIV/

73 In support of this conclusion, secondary materials have challenged the 'linkage' provisions for giving greater priority to protection of the monopolies of transnational corporations over the provision of essential medicines to Costa Ricans. Macaya R., 'El TLC, las medicinas y los argumentos utilizados', *op.cit.*, p. 3; Defensoría de los Habitantes, *op.cit.*, p. 18.

AIDS, had test data protection existed at the time. The CCSS included nelfinavir on the Medicines List (LOM) in December 1997. The CCSS purchased the branded version of nelfinavir for the following three and a half years, until sometime in 2001. Over that period, the CCSS paid a constant price for the drug of around USD 1.35 per unit. After that period, the CCSS purchased a generic version of the drug which reduced the price to USD 0.81 per unit in 2001, USD 0.62 in early 2003 and USD 0.5 per unit by late 2003. Assuming that test data protection had existed in 1997 and that the five year protection period began on that data, the test data protection would have allowed exclusive pricing to continue until December 2002. After that period, the generic producers would have had to seek registration and participate in public bids to supply the CCSS with the generic version of nelfinvar, a period Macaya estimates to be about one year. Potentially, that means that the CCSS might have had to continue paying USD 1.35 per unit from 2001 until 2003, resulting in an additional cost to the CCSS of USD 3.66 million over the 2.5 to 3 year period which, the author argues, would have been a considerable burden given the overall size of the CCSS's medicines budget of around USD 70 million annually.[74]

This is of course only one example and does not give any indication of the overall impact of extended market exclusivity on drug prices more generally. Indeed, pricing policies of pharmaceuticals depend on several factors, not only the existence of intellectual property protection. For example, where there is no generic equivalent of an innovator pharmaceutical, the innovator drug could still enjoy market exclusivity and have a higher price, even in the absence of test data or patent protection. On the other hand, low market interest in a pharmaceutical might force down prices even where intellectual property protection grants market exclusivity to the producer.

The economic modelling exercise helps to understand the impact of CAFTA on drug prices in a more systematic way. A joint programme of the International Centre for Trade and Sustainable Development (ICTSD), the World Health Organization (WHO), the Pan-American Health Organization (PAHO), the World Bank Institute and the United Nations Development Programme (UNDP) has developed a common methodology to determine the impact of TRIPS-plus provisions on public health. The common methodology consists of an aggregated Partial Equilibrium Model which assesses the impact of the provisions on the pharmaceutical market as a whole as well as on distinct therapeutic classes.[75] A joint project between the Centro Internacional de Política Económica para el Desarollo Sostenible (CINPE), the International Centre for Trade and Development and the World Health Organization undertook the modelling exercise of the TRIPS plus provisions of CAFTA to assess their future impact on access to medicines, including on drug prices.[76]

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74 Macaya, R., 'The Economic Consequences of an Overprotection of Intellectual Property Rights in CAFTA', *op.cit.*, pp. 4f.

75 Roffe, P., D. Vargas-Eugui and G. Vea, *Intellectual Property, Public Health, and Primary Health Care in FTAs and EPAs: A Shift in Policy?*, Paper on file with the author.

76 Hernández-González et al, *op.cit.*

The preliminary assessment of Costa Rica uses a 20 year base line and considers the impact of CAFTA in relation to 132 active ingredients, taking into account price evolution, population growth, elasticity and the level of exclusivity of the pharmaceutical products. The 132 active ingredients represent 80 percent of the CCSS budget from 2007.[77] The assessment models four different scenarios:

1. A TRIPS compatible scenario assuming implementation of the TRIPS Agreement without the TRIPS plus provisions of CAFTA. According to the model, the CCSS budget for pharmaceuticals would be USD424 million by 2020 and USD1052 million in 2030;
2. A 'CAFTA - -' or pro-competition scenario assuming compatibility with CAFTA but where the implementation of the intellectual property provisions is done in such a way as to favour competition from generic drug manufacturers – limited patent restoration due to administrative delays, maximum six years protection of test data (one year to apply plus five years protection) and no use of 'linkage' mechanism to obstruct entry of generics into the Costa Rican market. According to the model, by 2020, this could lead to an increase in CCSS spending on pharmaceuticals of USD 87 million in comparison to the TRIPS compatible scenario, and by 2030 an increase of USD176 million. Alternatively a 17 percent reduction in pharmaceutical consumption could avoid an increase in the CCSS budget in 2020 and a 14 percent reduction in pharmaceutical consumption could avoid an increase in the CCSS budget in 2030;
3. A 'CAFTA -' scenario assuming compatibility with CAFTA that is less pro-competitive than the previous scenario. This scenario includes the same assumptions as the 'CAFTA - -' scenario with two additional assumptions. First, patent owners seek to use the 'linkage' mechanism to obstruct 53 percent of applications for marketing authorization leading to a four year process to resolve the conflict. Second, the relaxed requirements to obtain patent protection increase the number of active ingredients subject to patents entering the CCSS's Official List of Medicines by 50 percent. According to the model, by 2020, this could lead to an increase in CCSS spending on pharmaceuticals of USD 87 million in comparison to the TRIPS compatible scenario and by 2030 an increase of USD240 million. Alternatively a 17 percent reduction in pharmaceutical consumption could avoid an increase in the CCSS budget in 2020 and a 19 percent reduction in pharmaceutical consumption could avoid an increase in the CCSS budget in 2030;
4. A 'CAFTA +' scenario assumes that the government has reduced-capacity to meet the requirements of CAFTA and includes two additional assumptions to the model. First, 33 percent of patent applications take more than 5 years to process and 7.3 percent of patent examinations take longer than 3 years, leading to patent restoration of one year for these patents. Second, the relaxed requirements for patents lead

77 Hernández-González et al, *ibid.*, p. 17.

to a 100 percent increase in the number of patented pharmaceuticals entering the CCSS Official List. According to the model, by 2020, this could lead to an increase in CCSS spending on pharmaceuticals of USD 87 million in comparison to the TRIPS compatible scenario, and by 2030 an increase of USD297 million. Alternatively a 17 percent reduction in pharmaceutical consumption could avoid an increase in the CCSS budget in 2020 and a 22 percent reduction in pharmaceutical consumption could avoid an increase in the CCSS budget in 2030;

5. Finally, a 'CAFTA ++' scenario assumes an aggressive pricing policy by patent holders charging four times the price for patented pharmaceuticals in comparison to the price under competitive conditions. In addition, the model assumes four-year delays for marketing authorization, five years protection for test data and a fifty percent increase in the number of patented pharmaceuticals entering the CCSS Official List due to relaxation of patent requirements. According to the model, by 2020, this could lead to an increase in CCSS spending on pharmaceuticals of USD 117 million in comparison to the TRIPS compatible scenario, and by 2030 an increase of USD331 million. Alternatively a 22 percent reduction in pharmaceutical consumption could avoid an increase in the CCSS budget in 2020 and a 24 percent reduction in pharmaceutical consumption could avoid an increase in the CCSS budget in 2030.

Tables III.8 and III.9 summarize the relevant results from the Economic Model.

Table III.8: Increase in the CCSS pharmaceutical budget

	TRIPS compatible budget (USD)	CAFTA - - (increase on base line)	CAFTA -	CAFTA +	CAFTA ++
2020	424 million	87 million	87 million	87 million	117 million
2030	1052 million	176 million	240 million	297 million	331 million

Table III.9: Decrease in drug consumption to avoid increase in CCSS budget

	TRIPS compatible	CAFTA - -	CAFTA -	CAFTA +	CAFTA ++
2020	0	–17 percent	–17 percent	–17 percent	–22 percent
2030	0	–14 percent	–19 percent	–22 percent	–24 percent

Consequently, in light of the results of the economic model, it appears that not only is it likely that CAFTA will lead to extended market exclusivity for innovator companies and delays in the marketing of generic pharmaceuticals, but also to higher prices for brand pharmaceuticals generally. In order to respond, the CCSS will have to increase its budget devoted to the purchase of pharmaceuticals or alternatively individuals will have to reduce their consumption of pharmaceuticals, accessed from the public health system. A third option would require a partial increase in the CCSS budget and a partial reduction in use of pharmaceuticals supplied through the public

sector. In light of this, it is now possible to consider the impact on the enjoyment of human rights.

5.4 Step three: Impact on human rights

Does CAFTA complement human rights?

CAFTA might complement human rights in two potential ways. First, the TRIPS plus provisions might strengthen the right to the protection of the moral and material interests of authors and inventors, including through the provision of a right to a remedy in the case of a breach. Relatively little support was available to support this hypothesis. The report 'Estado de la Nación', which considered the implications flowing from each of the Chapters of CAFTA, including Chapter 15 on Intellectual Property, suggested that the strengthening of judicial enforcement through Chapter 15 of CAFTA would not only contribute to the construction of a solid judicial framework for the application of civil, penal and administrative norms generally, but also specifically provide guarantees for individual authors and inventors.[78] The Constitutional Court has highlighted the need to balance the Constitutional right of inventors to protection of their intellectual property with the human right to health, which does suggest at least a link between CAFTA and the promotion and protection of the Constitutional rights of inventors.[79] The potential for CAFTA to strengthen the incipient local research in biotechnology also arose in the public debate prior to the Referendum.[80]

However, discussions with key informants and most other secondary materials did not make the connection between CAFTA and the promotion of inventors' rights. Instead, discussions revealed that there is almost no research and development in pharmaceuticals in Costa Rica – currently only two laboratories are undertaking research, while the most significant research occurs in North America and Europe. Discussions with the Patent Office revealed that few nationals apply for patent protection and few patents are granted to nationals. For example, in 2004, Costa Rica granted 37 patents, of which only 3 were granted to Costa Rican nationals.[81] As of September 2008, according to the Patent Office, there were currently 25 patent applications from nationals in comparison to 687 applications from foreign applicants.

As previously noted, Costa Rica has already implemented the TRIPS Agreement and there is little evidence to suggest that the extension of market exclusivity provided by CAFTA was necessary as a means to stimulate pharmaceutical innovation in Costa Rica. Indeed, discussions during the case study revealed that obstacles to local innova-

78 Alonso, E., A. Castro, *op.cit.*, pp. 36f.
79 Sala Constitucional de la Corte Suprema de la Justicia, Resolución 2007-09469, 3 July 2007.
80 'TLC y acceso a medicamentos: mentiras calculadas', article in La Prensa Libre, Michelle Coffey, 21 de marzo de 2007.
81 González Rodríguez et al, 'Secundo Curso', *op.cit.*

tion were not a lack of intellectual property protection but rather financial or other incentives to support innovation, as well as the small size of the local market. Strengthened intellectual property protection through the incorporation of the TRIPS plus provisions of CAFTA would be unlikely to alter this situation. Moreover, the concentration of pharmaceutical innovation in the hands of enterprises suggests that the human right to the protection of the moral and material interests of individual innovators would be met more directly through appropriate remuneration and employment conditions, rather than strengthening intellectual property protection. Consequently, CAFTA is unlikely to have a significant positive effect on the right of individual innovators to the protection of their moral and material interests given: (1) current low levels of research; (2) lack of additional factors beyond strong intellectual property protection (infrastructure, start-up investment) to stimulate research; (3) dependency on larger, established research efforts overseas.

The second hypothesis considers whether the TRIPS plus provisions might promote medical research and therefore improve the quality and quantity of pharmaceuticals in Costa Rica, resulting in a positive impact on the right to health in Costa Rica. While intellectual property protection has a role in stimulating medical research, discussions during the case study revealed that intellectual property protection has an equally significant effect on obstructing competition from generic pharmaceutical companies – which, in a country such as Costa Rica, could in fact limit access to new medicines and the right to health. Indeed, during the course of this case study, the European Commission released a preliminary report on the effects of patents on competition in the pharmaceutical industry. The report concluded that patents are key to the industry as a means of recouping investment in medical research and as a reward for innovation. However, the report also noted the anti-competitive practices of pharmaceutical companies, giving the example of the filing of up to 1,300 EU-wide patents over a single pharmaceutical product involving some 700 cases of litigation with generic companies. The report concludes that the significant costs caused by delays can be very significant to public health budgets and ultimately consumers.[82]

Further research would be necessary to indicate the extent to which increased profits in Costa Rica as a result of strengthened intellectual property protection might have an impact on stimulating medical research in that country. Such an exercise would be complicated and beyond the resources of the present study. For example, while the Pharmaceutical Research and Manufacturers of America (PhRMA) has proposed to elevate Costa Rica to the Priority Watch List of the US Trade Representative for its supposed deficiencies in its intellectual property regime, the organization was nonetheless unable to estimate the damage caused to the industry as a result of those deficiencies.[83] Without this information, it would be difficult to assess the extent

82 European Commission, 'Pharmaceutical Sector Inquiry', Preliminary Report, Director General Competition Staff Working Paper, November 2008, p. 5.

83 See: 'Special 301 Submission 2008', Pharmaceutical Research and Manufacturers of America, (PhRMA) (available at: http://www.ustr.gov – accessed 20 January 2008).

to which CAFTA might complement the right to health by promoting medical research. Further, as noted by the European Commission's report, strengthened intellectual property protection might not necessarily lead to increased innovation, but rather anti-competitive practices, which could restrict access to medicines. Consequently, the assessment concludes that insufficient information is available to estimate the potential positive or complementary impact that TRIPS plus intellectual property protection might have on promoting the right to health through stimulating medical research.

Does CAFTA affect the capacity of the government to fulfil the right to health?

The extension of market exclusivity and the consequent impact on the prices of pharmaceuticals is likely to put additional pressure on the budget of the CCSS and its capacity to ensure universal access to essential medicines. The CINPE/ICTSD Partial Equilibrium Model indicates that the CCSS might have to increase its spending on pharmaceuticals by as much as USD 331 million in 2030 in comparison with current spending levels, in order to avoid a 24 percent drop in consumption of pharmaceuticals supplied through the public sector. This appears to be a considerable increase. However, it is also important to put the figure into perspective. While CAFTA could result in a significant increase in the pharmaceutical budget, this represents a smaller increase when considered in light of its overall budget. For example, the pharmaceutical budget of the CCSS budget represents approximately 10 percent of the overall CCSS budget. A worse case scenario of a 24 percent increase in the pharmaceutical budget by 2030 is still a relatively small increase when viewed in terms of the overall CCSS budget. Nonetheless, the CINPE/ICTSD study concludes that CAFTA will lead to increased pressure on the capacity of social security and drug procurement systems.[84] It is also possible that the additional pressures on social security systems could divert funds away from improving prevention, creating infrastructure, health services and education.[85]

The representative of the CCSS was very clear in stating his belief that the TRIPS plus provisions would not affect the institution's capacity to meet universal access to essential medicines. First, he noted that the budget of the CCSS devoted to supply of essential medicines was increasing every year in any case and that the institution had been able to assume these increases.[86] The fact that the drug purchasing budget was only around ten percent of the overall CCSS budget indicated that increases in the pharmaceuticals' budget might be absorbed in the overall budget. However, this would clearly require sacrificing other social security services, thus potentially leading to retrogression in other social security areas. Moreover, the Pan-American Health Organization has noted difficulties that the CCSS already faces in meeting increases

84 Hernández-González et al, *op.cit.*, p. 31.
85 Roffe et al, *op.cit.*
86 Discussions with Albin Chaves, Director of Pharmatherapy, CCSS, 12 November 2008.

in its pharmaceutical budget, even prior to the full effects of the TRIPS Agreement being felt, leaving aside the impact of the TRIPS plus provisions of CAFTA.[87] Further, the Government is unlikely to be of immediate assistance in supplementing the CCSS pharmaceutical's budget as it is significantly behind in its contributions to the CCSS budget already.[88]

Second, the CCSS noted it was working on several strategies to help mitigate the impact of CAFTA on drug prices. For example, the CCSS was attempting to increase coordination with other Central American and Latin American countries to negotiate drug prices jointly to help reduce prices. Similarly, he noted that the CCSS had relied on parallel importing, and would continue to do so, and the Government also had the option of compulsory licencing. It is important to note that the protection of test data, including in relation to pharmaceutical products produced under compulsory licence, appears to reduce the effectiveness of this option by potentially delaying marketing authorization of the generic drug. Further, the CCSS has noted that the most significant factors affecting access to essential medicines were not intellectual property protection but rather the relative scarcity of certain active ingredients and pharmaceutical preparations included in the national drug strategy; the lack of generic drugs for some high cost pathologies such as cancer; and, deficiencies in the internal chain of supply of drugs.[89] These factors continue to influence universal access to medicines with or without CAFTA.

Nonetheless, it is clear that CAFTA will increase pressure on the CCSS budget if it is to meet its current levels of universal access to essential medicines. The extent to which this affects the Government's capacity to fulfil its obligations toward the progressive realization of the right to health depends in part on the strategies the CCSS adopts to mitigate the impact of rising drug prices. The strong institutional framework developed over several decades which supports universal provision of essential medicines is likely to provide a good basis for its continuation.

Another factor that will have a significant influence on the CCSS capacity to fulfil the right to health is the strategy adopted by innovator pharmaceutical companies with regard to how they use their intellectual property rights. If companies use stronger intellectual property protection to pursue aggressive pricing strategies, this could considerably increase the burden on the government. This in turn raises the extent to which pharmaceutical companies are meeting their obligation to respect the right to health. The growing recognition by States and the SRSG on the issue of Human Rights and Transnational Corporations and Other Business Enterprises, Mr. John Ruggie, that business enterprises also hold duties to respect human rights, makes pharmaceutical companies much more than mere commercial agents. They also hold responsibilities

87 Organización Panamericana de la Salud & Ministerio de Salud de Costa Rica, *Perfil del sistema de servicios de salud de Costa Rica*. San José, 2004 cited in Henández-González, *op.cit.*, p. 31.

88 The CINPE/ICTSD study reports that the Government is some USD 4.6 million behind in its contributions to the CCSS. CINPE/ICTSD, *ibid.*, p. 31.

89 CCSS, *op.cit.*, p. 3.

to the communities and the extent to which companies meet their human rights duties could have an impact on universal access to essential medicines in Costa Rica.

On the information currently available, it is clear that the TRIPS plus provisions in CAFTA will strain the capacity of the Government and the CCSS to meet its obligations to fulfil the right to health. Some of the additional costs might be absorbed in the CCSS budget but, given the current financial pressures on the CCSS, there are limits to which costs can be absorbed. This raises the risk of costs being passed on to users of pharmaceuticals, either through a reduction in the quality or quantity of drugs provided. However, the level of strain on the CCSS budget will also depend on the strategies taken by the CCSS and the Government to reduce prices – for example, through bulk purchasing – and the extent to which innovator companies rely on strengthened intellectual property protection to pursue aggressive pricing strategies.

Does CAFTA breach the right to health of Costa Ricans?

In spite of the confidence of the CCSS representative that the Government would deal with the increased pressure on its capacity to ensure universal access to essential medicines, the option remains that the government might respond to higher prices by revising its Official Medicines List in such a way as to avoid patented pharmaceuticals or to diminish the quantity of pharmaceuticals purchased. This could result in problems arising in relation to the 'availability', 'accessibility' or the 'quality' of essential medicines. A report of the Defensoría de los Habitantes raises this possibility, noting that the TRIPS plus provisions could, in some cases, lead to choices of products that might be less safe or efficient when compared to innovator products.[90] This in turn could affect the quality of health services and the quantity of medicines available through the public health system, and consequent regressions in the enjoyment of the right to health. Alternatively or in addition to reductions in the 'quality' of pharmaceuticals, the 'availability' of pharmaceuticals might suffer. Indeed, the CINPE/ITCSD/WHO modelling exercise indicates that if the CCSS cannot absorb the additional costs due to CAFTA, consumers will have to reduce their consumption of publicly provided medicines by up to 24 percent by 2030 (see Table III.9).

This in turn could affect the 'accessibility' of pharmaceuticals. Some key informants during the assessment expressed fears that this could lead to a two-tiered service in Costa Rica: a public sector service providing universal access to certain essential medicines, but not to all, and a second level of service, provided by the private sector, supplying higher quality medicines and services to those who can pay.[91] Indeed, there appears to be some evidence that this is occurring already, even without the implementation of the TRIPS plus provisions. A study prepared by the Ministry of Health

90 Defensoría de los Habitantes de la República, *op.cit.*, p. 24.

91 Discussions with Roman Macaya, indepedent expert, 21 November 2009; and, Alvaro Camacho, ASIFAN, 14 November 2009.

released in November 2008 revealed that Costa Ricans spend 30 percent of the total amount spent on health care in Costa Rica (including purchase of pharmaceuticals, consultations with doctors and odontology) on private health care.[92] Reductions in public sector provision of pharmaceuticals are likely to affect poorer households disproportionately. Studies indicate that poorer households have lower access to private health services and therefore rely more significantly on the social security system.[93] This in turn could have discriminatory effects, for example, on Nicaraguans and undocumented migrants who are disproportionately represented amongst the poor and therefore at higher risk.

However, the relatively strong human rights infrastructure in Costa Rica provides a buffer which should mitigate the worst effects of CAFTA being passed on to Costa Ricans. Two aspects of the institutional structure are important. First, there is strong judicial protection of the right to health in Costa Rica. Accordingly, individuals have access to the relatively rapid and uncomplicated *amparo* remedy which allows individuals to petition the Constitutional Court in writing seeking an order that the CCSS purchase a prescribed pharmaceutical which the CCSS does not normally provide through its Official List. The remedy is frequently used, the Constitutional Court processes them quickly and the CCSS respects the decisions. Second, the national human rights institution, the Defensoría de los Habitantes, also receives complaints in relation to public health services, most of which relate to access to medicines. In comparison to the *amparo* remedy which is rapid, does not involve a hearing, and provides an enforceable decision, the Defensoría undertakes an investigation into the claim which, although taking more time, includes consultations with the parties, with a view to finding a mutually agreeable settlement.

These two mechanisms may help to avoid at least the worst potential impacts of CAFTA being passed down to individuals. Indeed, the Constitutional Court has made its views clear in its Advisory Opinion on July 2007 that, whatever the impact of CAFTA on access to medicines, the Government must absorb them rather than pass them down to individuals, given the constitutionally protected right to health.[94]

Public participation provides a third 'institution' which could help to protect the right to health in the context of strengthened intellectual property protection. This is dealt with separately below given its direct relationship with the impact of CAFTA on human rights.

Nonetheless, the solid democratic institutions might not be able to protect the right to health in all cases. In spite of the relative ease of the *amparo* remedy, wealthier or better educated people might be more disposed to rely on the justice system to seek relief. In particular, while the remedy is awarded without representation of the parties, reliance on a legal practitioner might improve the chances of the application being in

92 'Ticos gastan c245 000 millones al año en medicina privada', Nación, 3 November 2008.

93 Organización Panamericana de la Salud & Ministerio de Salud de Costa Rica, *Perfil del sistema de servicios de salud de Costa Rica*. San José, 2004, cited in Henández-González, *op.cit.*, p. 32.

94 Sala Constitucional de la Corte Suprema de la Justicia, Resolución 2007-09469, 3 July 2007.

the right format with all relevant information for the Court to grant a remedy.[95] This could leave poorer people without access to a remedy. Moreover, judicial and quasi-judicial remedies might not necessarily lead to systematic responses to the impact of stronger intellectual property protection. Indeed, discussions with the CCSS revealed a certain frustration that the *amparo* remedy was distorting the systematic approach to the provision of essential medicines by requiring the CCSS to devote part of its budget to provide individualized treatments, drawing away from a focus on provision of medicines relevant to the widest number of patients. The result could skew the public health system in favour of those with access to remedies. Further, while the Constitutional Court has stipulated that the Government must take responsibility for fulfilling the right to health no matter what the consequences of its economic policies, the fact that the Government is already in debt to the CCSS indicates that there could be a gap between judicial reasoning and economic reality. It remains to be seen whether the Constitutional Court will provide a means of forcing the Government to fulfil its duties or whether economic pressures will expose the limitations of judicial enforcement of human rights.

The reality is that, in the absence of an increase in the CCSS budget to deal with the impact of intellectual property protection, the CCSS will have to absorb the additional costs in some way and there is a possibility that either the quality or quantity of medicines supplied through the CCSS might have to give. The institutional framework supporting the right to health in Costa Rica should be able to diminish the worst manifestations of this impact, but those protections might not work for all individuals. This could have the effect of encouraging wealthier people to move to private insurance, which could accentuate inequalities in society with a growing private sector focusing on a wealthier section of the population and an under-resourced public sector focusing on those who cannot afford private insurance.

Do CAFTA's enforcement provisions threaten enforcement of human rights?

CAFTA includes relatively strong provisions on enforcement, both of intellectual property rights nationally, through Article 15(11), and internationally. First, at the international level, the possibility arises that the US might rely on international dispute to restrict Costa Rica from implementing CAFTA in a flexible way that makes optimal use of flexibilities to protect the right to health. The process of US Certification of Costa Rica's intellectual property laws has probably provided a means of avoiding future inter-state disputes arising, as the two countries appear to have agreed that Costa Rican laws and regulations are in conformity with the agreement. However, situations might arise where public health crises could result in the Costa Rican Government revising that legislation – for example, relaxing test data protection in relation to compulsory licences. Unfortunately, in cases where disputes arise, international

95 Discussions with Richard Stern, human rights activist in Costa Rica, 26 November 2008.

arbitration has tended to treat disputes as commercial problems and human rights concerns have little role, if any at all.[96] On a positive note, Chapter 20 of CAFTA provides for the possibility of the submission of *amicus briefs*, upon agreement of the parties to the dispute. Human rights organizations could attempt to use this mechanism as a means of protecting the right to health in the context of dispute settlement. Human rights organizations could also seek to use the Inter-American Commission and the Court to increase pressure on the government in favour of the right to health, although these mechanisms have weaker enforceability of their decisions.

Second, at the national level, the question arises whether compliance with enforcement of intellectual property protections in accordance with Article 15(11) of CAFTA could threaten the various institutional protections of the right to health in the event of a contest between protecting an individual's right to health and protecting corporate intellectual property. The Advisory Opinion of the Constitutional Court of July 2007 seems to suggest that the fundamental nature of the right to health would have to prevail. To achieve this, the Court relies on the various exceptions in CAFTA, as well as the Doha Declaration on TRIPS and Public Health.[97] However, it is interesting to note that the Court accepts uncritically that the TRIPS plus provisions are equivalent to the protections of authors' rights in Article 47 of the Constitution relying on trade exceptions to protect the right to health. An alternative interpretation could distinguish CAFTA's strong intellectual property provisions from the Constitutional protection of authors' rights and simply hold that the fundamental right to health would prevail in the case of any inconsistency.[98] In any case, the clarity with which the Court has held that the CCSS, and not the individual, would have to bear the brunt of any negative impact of CAFTA, such as higher drug prices, suggests that nationally, legal enforcement of CAFTA's provisions should not threaten the right to health.

The threat posed by CAFTA's enforcement provisions relates less to the US commencing litigation and more to the combination of political pressure and the *threat* of legal action. Indeed, the whole process of US Certification of Costa Rican laws appears to suggest a high degree of concern on behalf of the Government to meet the demands of the US in order to *avoid* problems arising. With the certification process now complete, the annual 301 Reports of the US Trade Representative take over as a means of maintaining political pressure and the possibility of legal action. These reports, to which PhRMA makes annual submissions, have placed Costa Rica on the Watch List in recent years due to its intellectual property laws. A serious concern exists that the potential threat of US legal action, combined with continuous political

96 United Nations, 'Protect, Respect and Remedy: a Framework for Business and Human Rights', Report of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises, Human Rights Council, (A/HRC/8/5: para 37).

97 Sala Constitucional de la Corte Suprema de la Justicia, Resolución 2007-09469, 3 July 2007, Section XI(c).

98 *Ibid.*

pressure, could have a 'chilling' effect on Costa Rica taking action to protect the right to health.

What is the impact of CAFTA on the right to take part in the conduct of public affairs?

Unlike the other potential impacts considered in this assessment, this impact has both *ex post* as well as *ex ante* aspects as it is possible to examine the extent to which the government has respected the right to take part in the conduct of public affairs during the negotiation and adoption of CAFTA as a means of assessing likely future impacts of CAFTA on this right. Indeed, the Costa Rican experience of CAFTA provides an interesting case study of the right to take part in the conduct of public affairs in itself. As a general statement, Costa Rica demonstrates strong enjoyment of this right.

The Ministry of External Trade (COMEX) has documented its commitment to a process of consultation with different national sectors to establish the national negotiating position. Consultations involved business, cooperatives, trade unions, environmental groups, consumer organizations, academics, religious groups, and organizations working in the area of gender amongst others.[99] Consultation with civil society occurred in two ways: first, the Government provided information on the negotiation process and created the space for national consultation; and second, the various sectors were expected to commit time and resources to contributing to the consultation process.[100] It should be noted that participants in the case study expressed a certain degree of skepticism of COMEX's efforts to consult. Most key informants were critical of the process of participation, noting that it was one thing to appear to promote public participation and another to take the opinions of participants into account when forming public policy. Representatives of the innovator pharmaceutical industry, the generic pharmaceutical industry and non-governmental organizations stated that they did not have access to negotiators. A report of the Defensoría de los Habitantes suggests that there was not an active participation and significant representation of public health officials in the negotiations concerning CAFTA and representatives had difficulties in accessing versions of the negotiation text.[101] Discussions with the Ministry of Health would appear to confirm this, noting that a representative of the

99 Ministerio del Comercio Exterior (COMEX), *Información, Consulta y Particpación con la Sociedad Civil Costarricense en la Negociación del TLC*, 6, July 2003, pp. 9f.

100 Ministerio de Comercio Exterior, *Información y Consulta a la Sociedad Civil en el Proceso de Negociación del Tratado de Libre Comercio República Dominicana-Centroamérica-Estados Unidos*, August 2004, (available at: http://www.comex.go.cr/difusion/usa/default.htm – accessed 6 November 2008), p. 9.

101 The report notes communications from the Minister for Health and the Executive-Director of the CCSS to the Minister of External Trade in February 2003 and again in November 2003, reminding the Minister of the human right to health care, requesting consultations and making a series of nine recommendations concerning access to medicines, only one of which was eventually integrated in the negotiating text. The report cites the following official communications: 'Oficio DM-2004-03 del 19 de febrero del 2003' and 'Oficio 39.5222 del 24 de noviembre del 2003'. Defensoría de los Habitantes, *op.cit.*, p. 10.

Ministry was not involved directly in the negotiations concerning TRIPS plus, in spite of the fact that the provisions relating to test data protection and 'linkage' clearly have an impact on the functioning of the Ministry.[102] The Report of the Defensoría further underlines the lack of transparency in providing negotiating texts, noting that the text was withheld from the Assamblea Legislativa for 'strategic reasons'. The Defensoría compares this situation with that in the US where the relevant legislation requires the negotiation text to be supplied to Congress.[103]

During the adoption phase, the controversial nature of CAFTA, in particular its provisions on intellectual property protection, spurred considerable public debate and the Government held a referendum, the first in the history of Costa Rica, on whether the country should ratify the treaty. The referendum, held in October 2007, was very close with some 51.5 percent of voters agreeing with the adoption.[104] Discussions revealed allegations of media bias in favour of the 'yes' vote and threats made to employees by employers regarding the repercussions of a failure to adopt CAFTA, although it was not possible to verify these for the purposes of this case study. However, there were no allegations that the referendum itself was manipulated. The Referendum is probably the first of its kind in relation to the adoption of a trade agreement and itself an indication of the high level of enjoyment of the right to take part in the conduct of public affairs in Costa Rica. Moreover, key informants noted that the process motivated public debate on issues of great significance to the population.[105] Another important aspect of participation during the adoption phase was the use of the Constitutional Court to seek an Advisory Opinion on a range of constitutional issues associated with the adoption of CAFTA. This provides an indicator of the level of faith in government institutions, as well as the awareness and willingness to use them to ensure the constitutionality of government actions.

A further issue arose in the course of the case study relating to participation during the implementation phase of CAFTA. As described in the 'Scoping' stage, Costa Rica agreed to make the entry into force of CAFTA subject to certification by the US of all the implementation laws passed in Costa Rica. Effectively, by its own act, Parliament granted its powers to discuss laws and regulations to the Executive which in turn negotiated with the US on the content of those laws and regulations. For example, during preparation of the current case study discussions with a Parliamentary Advisor revealed representatives of COMEX and the US Trade Representative were discussing the draft regulations for test data protection and Parliament had not received a copy of the draft. While this would appear to be a devolution of Parliamentary authority to the Executive and indeed a foreign country, it is important to note that drafts of laws and

102 Discussions with Dra Rodriguez and Marcela González, Ministry of Health, 14 November 2008.

103 Defensoría de los Habitantes, *op.cit.,* p. 11.

104 'Costa Ricans back US trade pact but Opposition Refuses to Recognize Result', *International Herald Tribune*, 7 October 2007, (available at: http://www.iht.com/articles/ap/2007/10/08/america/LA-GEN-Costa-Rica-US-Free-Trade.php – accessed 21 January 2009).

105 For example, discussions with Gabriela Arguedas, Parliamentary Advisor, 11 November 2008.

regulations, including the regulations on test data mentioned above, are still made public through the Gazette, allowing time for public discussion. The situation does nonetheless raise concerns of national sovereignty and underlines the power imbalances between the US and Costa Rica. It also sits in juxtaposition with the situation in the US where US law protects the primacy of US law over CAFTA, stipulating that no provision of CAFTA or its application that is inconsistent with US law shall have effect.[106]

Past experience therefore suggests mixed enjoyment of the right to take part in the conduct of public affairs in the context of CAFTA. In summary, the government has respected this right in the current context of the negotiation, adoption and implementation of CAFTA, although concerns arise that the strict form of participation and consultation has not always resulted in effective participation. However, it does indicate a level of respect for and confidence in institutions, as well as respect for freedom of expression and related rights, which helps to add to a democratic framework to support the right to health in the future stages of implementation and monitoring CAFTA.

Do CAFTA's 'values' undermine human rights 'values'?

A further issue that arose during the case study was the potential for the TRIPS plus provisions to skew trade towards the commercial interests of large foreign corporations and away from the rights and interests of individuals and communities and the principle of social solidarity. In its assessment of the impact of intellectual property provisions, the Defensoría labelled the debate over CAFTA and access to medicines as a moral discord, one that pits a 'possessive individualism' of commercial interests against a principle of 'solidarity'. Accordingly, CAFTA neglects the interests of the majority, fails to take into account the needs of future generations, and ignores the principle of 'solidarity' and peoples' right to development which promotes social responsibility, knowledge as common heritage, fair trade, transparency and protection of the environment. The Defensoría promotes an alternative vision of the world to CAFTA; one that promotes an important role for civil society and an institutional framework that protects the rights and interests of the most vulnerable.[107]

106 Dominican Republic-Central America-United States Free Trade Agreement Implementation Act, Section 102, states that: 'No provision of the [CAFTA] Agreement, nor the application of any such provision to any person or circumstance, which is inconsistent with any law of the United States shall have effect'.

107 Defensoría de los Habitantes, *ibid*., p. 27. Similarly, Macaya questions the priorities that underlie CAFTA and its TRIPS plus provisions, stating: 'The State of Costa Rica, which cannot even guarantee the security of its own citizens, now has to dedicate resources to protecting private monopolies of foreign transnational corporations so that they can charge more for medicines. What absurd priorities!': Macaya, R., 'El TLC, las medicinas y los argumentos utilizados' (available at: http://www.anep.or.cr.leer.php/ – accessed 3 October 2008), p. 3 (translation by the author).

It is difficult to make an assessment of the impact of CAFTA on 'values'. On the one hand, it is important to emphasize that the protection of commercial values can also be beneficial to human rights in creating economic growth. Of course there is no automatic relationship between growth and protection of human rights, but growth can be an important ingredient. Moreover, protecting commercial interests of innovator pharmaceutical companies can also be justified to an extent as recompense for the significant process of research and development, which can often result in years of trials and expense, sometimes leading to a dead end.[108] Discussions with a former innovator pharmaceutical industry representative also highlighted the economic challenges facing innovator pharmaceuticals companies relating to decreasing investment and increasing competition between innovator companies.[109] Whatever the pros and cons of intellectual property protection and of CAFTA, some incentives are probably necessary to promote medical research, with the flow-on benefits this offers to public health. The WHO has recently published a report including proposals that could act as alternatives or complements to intellectual property protection as a means of spurring medical research.[110]

However, at least in the context of its intellectual property provisions, CAFTA does place higher value on commercial interests in comparison to other imperatives, including the promotion and protection of human rights. The intellectual property provisions of CAFTA clearly benefit the commercial interests of innovators, although the extent to which this will have a serious impact on the public health system remains to be seen. While exceptions and the 'Understanding' annexed to CAFTA suggest ways to ensure compatibility between commercial values and human rights, pressure from the US has tended to erode at least some of these during the implementation phase. The failure to include any transition periods, to give Costa Rica time to implement the intellectual property provisions, demonstrates a preference for urgency in favour of the commercial interests of innovator companies in comparison to the developmental needs of Costa Rica.[111] The impact of this prioritization of commercial interests remains to be seen and should also be considered in the context of other aspects of CAFTA as well as the many other factors that influence universal access to essential medicines. As previously noted, the strong institutional framework supporting the right to health in Costa Rica should provide a buffer to ensure the continued promotion and protection of human rights.

108 CCSS, *op.cit.*, pp.39f.

109 Discussions with a former innovator pharmaceutical industry representative, 6 November 2008.

110 World Health Organization, *Public Health, Innovation and Intellectual Property Rights*, Report of the Commission on Intellectual Property, Innovation and Public Health, Switzerland, 2006.

111 The report of the Commission of Eminent Experts underlines the asymmetries between the US and countries of Central America in terms of development and capacity, as well as asymmetries in the results of CAFTA. For example, as a result of CAFTA, local industry must 'compete or die' with much larger US transnational corporations. Comisión de Notables, *op.cit.*, pp. 21-25.

5.5 Indicators in light of the introduction of the TRIPS plus provisions

Table III.10 reconsiders the various indicators identified in Table III.6 in light of the analysis in sections 5.1 to 5.4. As would be expected, most of the structural indicators remain unchanged. This is because these are relevant to the human rights framework underlying the assessment which is unlikely to be affected by CAFTA. The structural indicators are more relevant to identifying the normative and institutional human rights framework in place which could help to mitigate the negative impacts of CAFTA and optimize the positive impacts. However, changes to process indicators are perceptible in areas such as the per capita expenditure on access to essential medicines and the share of public expenditure on essential medicines in relation to private expenditure. As a result, some changes are expected in the outcome indicator, namely 'incidence of persons foregoing essential medicines' although changes to this indicator are qualified in light of the structural indicators (strong human rights framework) and the capacity of the CCSS to absorb and respond to additional costs of medicines due to CAFTA.

Table III.10 – Human rights indicators post implementation of CAFTA	
	Right to health – Article 12(2)(c) ICESCR – the prevention treatment and control of diseases
Structural	– Unchanged (S1) – Unchanged (S2) – Unchanged (S3) – Unchanged (S4) – Unchanged (S5) – Unchanged (S6) – Test data protection requirements could render compulsory licencing provisions ineffective (S7) – Unchanged (S8) – Unchanged (S9)
Process	– Unchanged (P1) – Likely to increase to between USD 218 and USD 247 per capita in 2030 assuming population of 5.6 million (P2) – Likely to increase between 17 and 22 percent by 2020 and between 14 and 24 percent by 2030 (P3) – Potentially under strain depending on the extent to of 'P2' and 'P3' (P4) – Share of private expenditure on essential medicines in comparison to public expenditure could increase depending on capacity of government to respond to increases in pharmaceutical prices (P5) – Budget appears flexible but could come under strain depending on level of price increases for pharmaceuticals (P6) – Likely to increase (P7) – Proportion likely to remain at 0 percent, particularly in light of potential obstructions to award of compulsory licences due to test data protection (P8) – Categories of vulnerable people unlikely to change (P9)
Outcome	An increase in the incidence of people foregoing access to medicines is possible but solid structural indicators could mitigate worst impacts. Much depends on the capacity of the CCSS to absorb additional costs due to CAFTA (O1)

6 STEP FIVE: CONCLUSIONS AND RECOMMENDATIONS

In conclusion, CAFTA is likely to strengthen the position of innovator pharmaceutical companies, by extending market exclusivity periods and allowing companies to increase prices for pharmaceuticals. The extent to which this will occur should not be exaggerated, but on the evidence presented this is the likely outcome. This in turn will place pressure on the CCSS budget, while reducing the market share for generic pharmaceutical companies. The CCSS could be faced with the choice of either increasing its pharmaceutical budget or decreasing the quality or quantity of pharmaceuticals provided through the public system: these pressures are likely to grow overtime. However, the extent to which these pressure threatens the enjoyment of the right to health depends on several other factors.

First, the strong human rights institutional framework comprising judicial protection of the right to health, the Defensoría de los Habitantes, an established tradition of universal provision of medicines and a vibrant and active civil society, should act as a buffer to avoid the worst effects of CAFTA being passed onto individuals. This should continue to provide strong protection to the right to health and ensure access to essential medicines. Second, the extent to which Government institutions can respond to the exigencies of CAFTA, for example, through avoiding delays in patent grants, will help minimize the extension of market exclusivity and reduce pressures on the CCSS. Third, the strategies of innovator pharmaceutical companies – whether they employ aggressive tactics to use intellectual property to raise prices or not – will have a significant effect on pharmaceutical pricing policies, as well as competition from generic pharmaceutical companies, which in turn will affect the level of pressure on the CCSS. Fourth, the Government can employ available strategies such as compulsory licences, parallel importing, or bulk negotiation and purchase of pharmaceuticals with neighbouring countries, to help ensure access to essential medicines and maintain lower prices.

In light of this, the following four recommendations are made. First, the Government should strengthen its institutional capacity to mitigate the potential impact of CAFTA. The case study revealed that the Government was already strengthening the Patent Office. Ensuring that the Patent Office and the Ministry of Health have adequate staffing and financial support should help to reduce the likelihood of resort to patent restoration, ensure against the award of bad patents (products that do not fully meet the requirements for patenting) and also deal with the impact of the 'linkage' provisions, particularly where 'linkage' leads to an increased number of challenges to applications for marketing authorization.

Second, the Government and civil society should place more focus on identifying the human rights responsibilities of pharmaceutical companies. Discussions during the case study revealed that civil society pressure to encourage pharmaceutical companies

to reduce prices has been effective.[112] However, it appears that the pressure is applied in an ad hoc manner, depending on the effort of individuals in civil society organizations and the presence of organizations concerned with particular conditions such as HIV/AIDS or cancer. The emergence internationally of a corporate duty to respect human rights could provide a means to move from ad hoc arrangements nationally, so that the encouragement of pharmaceutical companies to employ responsible pricing and distribution policies is comprehensive and regulated, including with the possibility of legal sanctions where necessary. In addition to clarifying the human rights responsibilities of pharmaceutical companies, the Government could also strengthen competition laws. Measures could include the introduction of fines against companies using the 'linkage' provisions to enter into litigation as a tactic to delay the entry of cheaper generics onto the market,[113] the use of compulsory licences to guard against anti-competitive practices, the strengthening of bulk-buying strategies already been pursued by the CCSS, and the provision of incentives to national generic producers, including to promote local innovation.

Third, the Defensoría de los Habitantes and civil society organizations should continue monitoring the implementation of CAFTA. Monitoring should occur at five levels: first, monitoring the CCSS essential medicines budget as well as both the quality and quantity of medicines supplied through the public system; second, monitoring pricing practices of innovator and generic companies and the extent to which pharmaceutical companies are meeting their duty to respect the right to health; third, monitoring *amparo* applications as well as complaints to the Defensoría to analyze patterns of complaints that might relate to the implementation of CAFTA; fourth, monitoring media for information on the practices of pharmaceutical and generic companies relating to access to medicines; and, fifth, monitoring the website of the USTR, in particular submissions for the annual 301 Report, to assess the level of pressure being placed by the US on Costa Rica to strengthen intellectual property protection further. The good practices of data collection and analysis in Costa Rica should make such monitoring relatively simple. A full *ex post* HRIA should then be undertaken in 2010 and 2020 with a view to assessing the real impacts of CAFTA, and comparing them to the results of this assessment, as well as the results of the CINPE/ICTSD Partial Equilibrium Model.

A fourth recommendation relates to the possibility of renegotiating the intellectual property provisions of CAFTA relating to access to medicines. It is worth highlighting that lobbying of US of Congress representatives subsequent to the Democrats taking control of Congress in 2006 had the result of softening some of the intellectual property provisions in free trade agreements with Colombia, Panama and Peru.[114]

112 Discussions with Richard Stern, AIDS and human rights activist in Costa Rica, 26 November 2008.

113 The CINPE/ICTSD study refers to the Australian 'Therapeutic Goods Act (1989)' which includes fines of up to AUSD10 million against patent holders that pursue litigation in bad faith in order to delay the entry of generics. Hernández-González et al, *op.cit.*, p. 35.

114 Roffe et al, *op.cit.*, p. 2.

Moreover, the Undertaking annexed to CAFTA, while not legally binding, envisages consultations in the case of inconsistencies arising between CAFTA and respect for the public health objectives of the solution resulting from the Doha Declaration on TRIPS and Public Health. This could provide a spring board to launch a new discussion on CAFTA, particularly in light of the requirement of test data protection, even in relation to drugs produced under compulsory licence, which would tend to claw back the relevance of compulsory licencing as envisaged in the Doha Declaration. This option is probably unrealistic at this stage, given that Costa Rica has only now finished a long process of legal reform to ensure compatibility. Nonetheless, it could provide a future strategy, particularly in light of results from monitoring implementation.

7 STEP SIX: MONITORING AND EVALUATION SECTION

The previous section has outlined steps for continued monitoring of the impact of CAFTA on human rights and access to medicines. Chapter IV presents an evaluation of the human rights framework for impact assessment of trade agreements, taking into account the experiences of applying the methodology in Costa Rica.

CHAPTER IV
BENEFITS AND RISKS OF HUMAN RIGHTS IMPACT ASSESSMENTS OF TRADE AGREEMENTS

1 INTRODUCTION

Having developed and illustrated a methodology for undertaking HRIAs of trade agreements, Chapter IV moves on to answer the two questions underlying the critical question of this thesis, namely:

1. *What benefits do HRIAs offer to the assessment of trade agreements?*
2. *What are the risks involved in undertaking HRIAs?*

Section 2 considers the first question by taking the six 'original' aspects of the human rights framework identified in Chapter I Section 4 and considers how these aspects are helpful in the specific context of analyzing trade agreements. The next section identifies the various risks involved in the framework. In considering the benefits and risks of HRIAs, Chapter IV relies on a mix of secondary materials and experience drawn from the Costa Rican case study. This provides the basis for the Final Observations which answer the research question posed in the Introduction to the present thesis.

2 BENEFITS OF HUMAN RRIGHTS IMPACT ASSESSMENTS OF TRADE AGREEMENTS

Chapter I identified six 'original' aspects of the human rights framework for impact assessment when compared to two social impact assessment frameworks. This section takes those six claims, and considers how they benefit the impact assessment of trade agreements. It is important to note that this section does not consider a range of beneficial aspects of HRIAs, such as the emphasis on popular participation or the general benefits flowing from the monitoring trade agreements, as these are also benefits related to other impact assessment frameworks. Instead, this section considers the benefits of only those aspects of HRIAs which are intrinsically related to the human rights framework.

2.1 A comprehensive framework

The first original aspect of the HRIA framework is its comprehensive nature which considers potential impacts of trade agreements on civil, cultural, economic, political and social rights. The comprehensiveness of the human rights framework should broaden the categories of impact considered during an assessment, covering not only

social and economic impacts, but also cultural and political impacts. It should also broaden the understanding of what is meant by 'social impacts' of trade agreements, providing a more complete framework for analysis. A drawback of the HRIA framework is that it does not include a framework to assess environmental impacts of trade agreements, an area where significant impacts can arise.

An illustration helps to provide a clearer understanding of these benefits, as well as the limitations of the HRIA framework. The European Commission's Trade and Sustainability Impact Assessment (TSIA) methodology and UNEP's Integrated Impact Assessment (IIA) methodology rely on an alternative global framework, namely the sustainable development framework that rests on the three pillars of sustainable development – economic development, social development and environmental protection.[1]

On one level the sustainability framework relied upon by both the TSIA and IIA methodologies could be considered more comprehensive than the HRIA framework. The inclusion of environmental protection in the sustainability framework is an important consideration in the assessment of trade agreements which HRIAs fail to consider in any depth. As already noted, the link between human rights and the environment, while important in practice, has been given insufficient attention at the intergovernmental level.[2] Similarly, the focus on economic impacts, while not entirely neglected in HRIAs, is nonetheless given prominence in the TSIA and IIA frameworks. It is true that the HRIA framework considers economic impacts as part of the causal-chain analysis linking the introduction of the trade measure to the impact on the human rights indicator. However, the sustainability framework makes examination of these impacts more explicit by including statements on economic impacts as well as social and environmental impacts in conclusions and recommendations. In this sense, the sustainability framework might be more comprehensive than the human rights framework.

On another level, HRIAs consider other impacts beyond only those considered by the sustainability framework. Importantly, the TSIA framework leaves out any systematic examination of the political and cultural impacts of trade agreements.[3] In terms

1 Johannesburg Declaration on Sustainable Development, Political Declaration of the World Summit on Sustainable Development, 4 September 2002, para. 5; European Commission, *Handbook for Trade Sustainability Impact Assessment*, European Commission, External Trade, Brussels, 2006, p. 28; United Nations, *Reference Manual for the Integrated Assessment of Trade-Related Policies*, United Nations Environment Programme, New York and Geneva, 2001, p. 20.

2 While UN Member States have not accepted nor elaborated a stand-alone human right to a healthy environment, the Human Rights Council has begun to consider the human rights implications of global environmental phenomena such as climate change. See United Nations, 'Report of the Office of the High Commissioner on the Relationship between Climate Change and Human Rights', Human Rights Council, 2009 (A/HRC/10/61): outside the intergovernmental arena, authors have devoted greater attention to the issue: see e.g.: Lubbers, R., W. van Genugten, and T. Lambooy, *Inspiration for Global Governance: The Universal Declaration of Human Rights and the Earth Charter*, Kluwer, the Netherlands, 2008.

3 See generally: European Commission, *Handbook for Trade Sustainability Impact Assessment*, European Commission, External Trade, 2006.

of cultural impacts, the IIA methodology does examine impacts on 'issues affecting minorities' and 'traditional knowledge and culture' although under the rubric of social impact.[4] In relation to political impacts, the IIA and TSIA frameworks do include consultations and promote participation in the assessment process itself, but they do not assess the respect for public participation as an entitlement in the process of negotiating and adopting trade agreement.[5] In contrast, HRIAs consider cultural and political aspects alongside social impacts as a point of departure. In short, the HRIA framework has strengths and limitations – on the one hand broadening analysis to include political and cultural impacts, but not going so far as to include environmental impacts to any significant degree. At this level of discussion, HRIAs might well complement other assessment frameworks.

The benefits of the comprehensive nature of the HRIA framework really come to the fore when comparing how HRIAs treat 'social impacts' in comparison to other frameworks. For example, the EU-Mercosur TSIA identified nine core economic, environmental and social themes or indicators based on the three pillars of sustainable development. Three of these nine themes were social themes: namely, 'poverty', 'health and education' and 'equity'. 'Poverty' was assessed in relation to employment levels, employment conditions (including forced labour), livelihoods and access to and affordability of essential services; 'health and education' was assessed in terms of public expenditure, prevalence of disease and access to and quality of health and education services; and 'equity' was assessed in relation to income equality and gender equality.[6]

The narrow understanding of 'poverty' in terms of employment outcomes and conditions contrasts with the more comprehensive human rights framework. The Committee on Economic, Social and Cultural Rights has defined poverty as 'a human condition characterized by sustained and chronic deprivation of the resources, capabilities, choices, security and power necessary for the enjoyment of an adequate standard of living and other civil, cultural, economic, political and social rights'.[7] An HRIA considering impacts of a trade agreement on poverty would therefore consider the

4 See e.g.: United Nations, *Reference Manual for the Integrated Assessment of Trade-Related Policies*, United Nations Environment Programme, New York and Geneva, 2001, p. 20; United Nations, *Handbook on Integrated Assessment of Trade-Related Measures: The Agriculture Sector*, United Nations Environment Programme, New York and Geneva, 2005, p. 20.

5 For information on the steps to ensure participation of and consultation with affected groups in the process of impact assessment see e.g.. UNEP, pp. 5-10. European Commission Handbook, *op.cit.*, pp. 23-28. However, the impact indicators focus on economic, social and environmental impacts.

6 University of Manchester, *Trade SIA of the Association Agreement under Negotiation between the European Community and Mercosur*, Update of the Overall Preliminary Trade SIA EU-Mercosur, Final Report, Institute for Development Policy and Management (University of Manchester), Chaire Mercosur, Copenhagen Economics, ECOSTRAT Consultants, GRET, Land Use Consultants, Natural Resources Institute (University of Greenwich), WISE Development, November 2007.

7 United Nations, *Poverty and the International Covenant on Economic, Social and Cultural Rights*, Statement adopted by the Committee on Economic, Social and Cultural Rights, 2001, (E/C.12/2001/10: para. 8).

types of potential poverty impacts in considerably more detail than in the EU-Mercosur assessment. Similarly, it is unclear why 'equity' is understood only in terms of income and gender equality. Discrimination and equality under human rights law considers not only gender equality but also discrimination and equality in relation to others such as indigenous peoples, persons with disabilities, minorities, migrant workers and so on.

Consequently, the HRIAs can benefit the assessment of trade agreements by broadening the range of impacts – political and cultural impacts not only social impacts – and broadening the understanding of what constitutes 'social impacts' – for example, not only gender equality but also equality in relation to the other categories of discrimination, not only economic poverty but other aspects of poverty. The principles of interdependence and inter-relatedness underlying the human rights framework highlight the importance of considering all potential impacts of trade agreements even though the assessment may eliminate unlikely impacts during the 'screening' stage. Nonetheless, the HRIA methodology is faced with the limitation of not including an assessment of environmental impacts and the HRIA gives less prominence to economic impacts. To maximize the benefits of the human rights framework and accommodate its limitations, consideration could be given to combining HRIAs with other assessments, such as environmental assessments of trade agreements.

The Costa Rican case study provides an illustration of how these benefits and limitations of the HRIA framework affect impact assessment. On the one hand, the human rights framework naturally led to an examination of political aspects as well as the institutional framework. These factors could potentially have a significant influence on the actual impact of intellectual property protection on access to medicines which other frameworks might not necessarily have examined automatically. The lack of an environmental aspect to the HRIA framework was not important to the case study given the specific focus on access to medicines and human rights. However, if the HRIA had examined other aspects of the chapter on intellectual property, such as the impact of accession to the UPOV Convention[8] and its impact on biodiversity and traditional knowledge, then the lack of an environmental dimension to the framework would have become more of an issue. A full assessment of CAFTA might have to consider the possibility of combining the HRIA framework with an environmental assessment.

On the other hand, the lack of an explicit economic dimension to the HRIA framework was not problematic. Indeed, the causal-chain linking the introduction of the TRIPS plus provisions to future impact on access to medicines and human rights made economic aspects explicit in any case and the Partial Equilibrium Model clarified these impacts. However, the lack of prominence given to economic impacts in the

8 Union pour la Protection des Obtentions Végétales ; Convention for the Protection of New Varieties of Plants.

HRIA framework might nonetheless underplay these impacts in future assessment exercise as the attention of the assessor might not immediately be directed to the consideration of economic aspects. Indeed, this raises a broader issue of the need to develop a deeper understanding of the economics of human rights. Possibly, one of the benefits of HRIAs of trade agreements might be to help do so.

2.2 A more objective standard

The second claim to originality is that the HRIA framework relies on an objective standard – human rights standards – as the standard of assessment. This provides a point of reference for the impact assessment which is both more objective and external to trade liberalization than the standards of measurement for other assessment frameworks. This moves the assessment away from focusing on what form, pace and sequencing of trade policies are most appropriate to meet the objective of trade liberalism to the identification of trade policies that meet the objective of human rights standards. In this way, trade liberalization becomes the object of assessment – and its compatibility with human rights norms and standards – rather than being the assumed or unquestioned end of trade policy. The benefit of using an objective standard of assessment is that it can broaden the scope and impact of trade assessment beyond choosing between two trade policy options to include a consideration of conceptual issues underlying trade policy such as what form of trade openness is most appropriate to improve peoples' lives. In this sense, HRIAs are potentially complementary to environmental impact assessments of trade agreements which also assess trade agreements against an objective assessment, namely the standards in multilateral environmental agreements.

The use of objective standards for impact assessments should help to deal with perceived weaknesses in existing trade impact assessment methodologies. For example, civil society groups have criticized the TSIA methodology for failing to consider a de-liberalization scenario which they claim demonstrates a pro-liberalization bias in the methodology.[9] The authors of the methodology have observed that a de-liberalization scenario was not on the negotiating table and was consequently not assessed.[10] Thus, for the TSIA framework, impact assessment becomes the function of trade negotiations. An HRIA cannot accept such a pro-liberalization stance uncritically as the primary objective of an HRIA is not to meet the objectives of a trade negotiation

9 International Federation of Human Rights (FIDH), *Human Rights Impact Assessment of Trade and Investment Agreements Concluded by the European Union*, February 2008, p. 12; EU Trade and Sustainability Impact Assessments: A Critical View', Statement of European Civil Society Organizations, October 2006, p. 3; Richardson, S., *A 'Critique' of the EC's WTO Sustainability Impact Assessment Studies and Recommendations for Phase III*, Oxfam GB, WWF-European Policy Office, Save the Children, Action Aid, March 2000, p. 2.

10 Kirkpatrick, C., and C. George, 'Methodological Issues in the Impact Assessment of Trade Policies: Experience from the European Commission's Sustainability Impact Assessment (SIA) Programme', *Impact Assessment and Project Appraisal*, 24(4), December 2006, 225-334, p. 239.

agenda but rather to assess impacts according to human rights standards. However, relying on an objective standard for assessment, such as human rights law, is relevant only to the extent that the human rights framework is capable of critiquing trade reforms and providing workable alternatives. This requires consideration of the extent to which HRIAs provide an effective analytical framework for trade agreements, the third unique aspect of the HRIA framework.

2.3 A developed analytical framework

The third claim to originality, that the HRIA framework provides a more developed analytical framework to strengthen the interpretation of an assessment, can be tested in two stages. The first stage examines the extent to which the human rights framework broadens and deepens the analysis of trade agreements. The second stage considers whether that analysis provides guidance to choosing different or better trade policies. In relation to the first stage, the principle of non-discrimination provides an illustration of how the human rights framework can broaden and deepen analysis of trade agreements. Again, it is helpful to consider an example from an existing trade impact assessment. The TSIA of the Euro-Mediterranean Free Trade Area examined, amongst other impacts, the potential impact of the Free Trade Area on 'equity', which it interpreted as 'income distribution' and 'gender equality'.[11] In relation to 'gender equality' the assessment concluded that 'significant gender impacts may occur …for agriculture, associated with a decline in traditional food production and the extension of commercial farming … increasing feminisation of the workforce is likely to be an impact in many countries, but with uncertain effects on gender equality, dependent on domestic policy'.[12] This conclusion throws up as many questions as it answers.

An HRIA would approach the analysis and express the conclusions quite differently. It would employ the terms 'non-discrimination' and 'equality' upfront and recognize that these terms have specific meanings. This would lead to an analysis based on human rights jurisprudence which would consider not only equality between men and women but also non-discrimination and equality in relation to others, such as indigenous peoples, persons with disabilities, and so on. The analysis would then consider the extent to which *de jure* or *de facto* discrimination currently exists and whether the trade agreement would have any impact on that discrimination, either positively or negatively. It would analyze current biases within society leading to indirect discrimination which in turn might result in the trade agreement exacerbating

11 University of Manchester, *Sustainability Impact Assessment of the Euro-Mediterranean Free Trade Area*, Final Report of the SIA-EMFTA Project, International Institute for Development Policy and Management (University of Manchester), Bocconi University, The International Centre for Advanced Mediterranean Agronomic Studies, Centre International des Technologies de l'Environnement de Tunis, Deloitte & Touche, Overseas Development Institute, UN Economic and Social Commission for Western Asia, 2007, p. 17.

12 Euro-Mediterranean TSIA, *ibid.*, p. 18.

discrimination and inequality or alternatively preventing the beneficial aspects of a trade agreement from taking effect.

The analysis would explain whether the 'increasing feminisation of the workforce' might be a continuation of a pattern of unequal work for women in employment sectors targeted as 'women's work', or whether the 'increasing feminisation' might provide women with new opportunities for quality work that could help break down past patterns of inequality. It would consider whether the feminization of the workforce also included women with disabilities or women from minorities, and whether multiple discrimination might occur if they were not. Further, the throw away reference to 'domestic policy' becomes central and in turn must be analyzed in relation to the extent that the State has laws and policies both preventing discrimination but also promoting equality, through equality laws – for example, equal pay for equal work – as well as through temporary special measures such as affirmative action schemes. Where there is discrimination, this must be justified according to reasonable and objective criteria. Where unjustified discrimination continues, then an individual should have resource to a legal remedy.

As can be seen, the human rights framework broadens and deepens the analysis considerably. It not only provides greater clarity to impacts by explaining, for example, what is meant by 'feminisation of the workforce', it identifies more clearly the nature of those impacts – whether this is a positive or negative development – and it also politicizes actors, focusing the spotlight not only on different women – women with disabilities, women from minorities and so on – but also on the State. In the TSIA, the State recedes into the background and 'domestic policy' appears to be an optional variable. In an HRIA, the State and potentially other actors such as employers take centre stage and have responsibilities to ensure that domestic policy not only exists but is directed towards prohibiting discrimination and promoting equality.

The example of non-discrimination is perhaps one of the better examples of the analytical framework of human rights given its relatively clear legal definition based on decades of national, regional and international jurisprudence. Many of the impacts of trade agreements on human rights affect economic, social and cultural rights, which are often considered to be normatively vague. A quick review of some of the provisions in the International Covenant on Economic, Social and Cultural Rights suggests that human rights law does not always offer a particularly rigorous framework to analyze the impacts of trade agreements. Nonetheless, the Committee on Economic, Social and Cultural Rights has done much to clarify the normative content of economic, social and cultural rights through its General Comments.

Hunt and MacNaughton build upon the Committee's General Comment No. 14 on the right to health to provide an analytical framework for right to health impact assessment. This requires the assessor to examine the impact of the policy under investigation on the 'availability', 'accessibility', 'acceptability' and 'quality' of health goods, facilities and services, as well as the underlying determinants of health as defined by the Committee, and on the six concepts of 'progressive realization', 'core obligation',

'equality and non-discrimination', 'participation', 'information' and 'accountability'.[13] The framework is less rigorous than the framework for analysis of discrimination given the comparative difficulties in measuring notions such as 'accessibility' or 'acceptability' or 'core obligation' or 'progressive realization' and also because some of these terms have not become human rights 'terms of art' in the same way as 'non-discrimination'. However, the growing body of jurisprudence on economic, social and cultural rights at the national, regional and international levels is giving greater definition to these concepts, helping to make their measurement more rigorous, reliable and valid. Consequently, while the human rights analytical framework might be stronger in relation to some rights over others (for example, non-discrimination in comparison to the right to health), it nonetheless provides a relatively rigorous analytical framework that helps to give meaning to the results of an assessment.

This leads to the second stage of considering the benefits of the analytical framework of HRIAs, namely whether the deeper and broader analysis provides a springboard to identify better trade policies. Claims that human rights law provides a framework for a rights-based approach to trade also suggest that human rights law and HRIAs could provide a new model for trade policy-making which raises the question whether this is in fact possible, and if so, how. Andrew Lang asks the question what precise role human rights play in providing policy guidance to trade policy-makers and concludes that, to date, human rights analysis has tended to reproduce existing arguments and policy prescriptions already familiar to trade practitioners.[14] While trade and trade agreements are clearly issues that can affect human rights, human rights standards might not be able to go the step further and propose original or innovative ways of regulating trade. Human rights treaties make few references to trade; and when they do, they give little indication of how human rights regulations should affect trade.

To give an illustration, in order to ensure freedom from hunger, ICESCR requires States to take steps to ensure an equitable distribution of world food supplies in relation to need, taking into account the problems of both food importing and food exporting countries.[15] While ICESCR clearly links agricultural trade with freedom from hunger, it does not provide the means of identifying how to do so. The natural

13 Hunt, P. and G. MacNaughton, 'Impact Assessments, Poverty and Human Rights: A Case Study Using the Right to the Highest Attainable Standard of Health', Submitted to UNESCO, 2006, Annex 4.

14 He summarizes the analytical process applied by human rights practitioners on trade agreements that includes: first, a description of the trade agreement under examination; second, the identification of the relevant human rights concerned affected by the trade agreement and an elaboration of their legal content and obligations on States; third, an assessment of recent experience to determine the effect of the trade agreement on trade as well as on a variety of social issues related to human rights such as food security, unemployment, poverty and social dislocation; and, fourth, a list of policy options designed to reconcile trade policy with the human rights identified – such as improved market access, stronger special and differential treatment for developing countries, the provision of further aid and special programmes for the poor. Lang, A.T.F., 'The Role of the Human Rights Movement in Trade Policy-Making: Human Rights as a Trigger for Policy Learning', *New Zealand Journal of Public International Law*, 5, 2007, 147-172, p. 156.

15 ICESCR, Article 11.

tendency is then to turn to existing options such as more special and differential treatment for developing countries, increasing financing for development, more effective food aid, special safeguards to protect against import surges, differentiating between developed and developing countries in relation to the form, pace and sequencing of trade liberalization, and so on.[16] This could be an important limitation to the relevance of HRIAs in providing guidance to trade negotiations or the implementation of trade agreements. An HRIA might favour some trade policies over others but will not necessarily provide new options. It is relevant to highlight that other impact assessment frameworks also face this limitation and so it does not go to the specific question of the added-value of HRIAs in relation to those frameworks. However, it is important to acknowledge the limitation in any case.

While human rights treaties might not provide significant guidance on what trade policies must or should be chosen over others, the principles and approaches of human rights law might nonetheless provide parallel experiences of similar concerns as a means of provoking new approaches to trade reform. This has been Lang's conclusion; he notes that '(e)ven if human rights are not in themselves a source of new policy ideas, human rights interventions into trade policy debates perform the crucial function of providing a trigger for policy learning, and helping to create the conditions in which learning is more likely'.[17] Consider for example the debates over the role of the State in human rights law and in trade law. The trade regime has struggled with the role of the State, permitting a more interventionist role for the State during the GATT and emphasizing a diminished role for the State during the period of the 'Washington Consensus', which had a strong influence over the Uruguay Round. This struggle continues in the context of the Doha Development Round of trade negotiations in the WTO and the discussion on TRIPS and public health. A fundamental question relates to how to reconcile 'free' trade with State intervention in the market.

In parallel, human rights law has also struggled with the role of the State as guarantor of freedoms. Some visions of human rights have focused on minimizing the role of the State in society, placing an emphasis on the preservation of individual autonomy and denying positive State obligations to ensure entitlements such as universal health care. While tensions continue to exist, human rights law today appears reconciled with the notion that freedom requires freedom *from* State abuse as well as freedom *through* State intervention as guarantor of basic entitlements. This could provide a parallel approach to stimulate trade thinking about the role of the State in 'free' trade. In this way, discussions on free trade could move beyond a juxtaposition of 'free' trade and 'protectionist' trade towards an acknowledgment that in order for 'free' trade to exist, the State must not only respect market freedoms but intervene to regulate markets without this necessarily leading to an overall preference for trade

16 See e.g.: United Nations, 'Globalization and its Impact on the Full Enjoyment of Human Rights', Report of the High Commissioner for Human Rights, Commission on Human Rights, (E/CN.4/2002/54: paras: 44-53).

17 Lang, *op.cit.*, p. 165.

protectionism. While human rights law would not provide the answers to how this can occur, it at least provides a means to provoke a re-thinking of trade regulation by reference to notions familiar to both regimes.

In a similar vein, the human rights notion of non-discrimination could provide food-for-thought to re-examine the trade principle of non-discrimination. The fact that the two regimes both include principles of non-discrimination is often considered a point in common. Yet the human rights notion of 'discrimination' is intrinsically related to the principle of 'equality'. This requires the State to go beyond merely prohibiting discrimination to ensuring that discrimination does not occur in practice. Thus, the State has to provide 'reasonable accommodations' to individuals to ensure that they can participate actively in society on the same level as others, ensuring that discrimination does not occur in practice. Similarly, the State must also adopt temporary special measures in favour of certain groups of people in order to combat the underlying biases in society that lead to discrimination – affirmative action.

This notion of affirmative action is not unknown to the trade principle of non-discrimination. Special and differential treatment in the form of the Generalized System of Preferences (GSP) exists as an exception to the MFN principle of non-discrimination. It makes allowances for the fact that goods and services from developing countries are not necessarily in an equal position of competition in international trade. Yet the GSP is treated as an exception only, which takes into account unequal positions in global trade but it does not seek positive discrimination in order to promote greater equality in international trading relations. Human rights law on the other hand recognizes that positive discrimination is sometimes necessary in order to ensure that discrimination does not occur in practice and to tackle the underlying biases in society with a view to achieving substantive equality. Ultimately, the Doha development agenda is seeking some way of reconciling the development concerns of developing countries with trade principles such as MFN and national treatment. The understanding of non-discrimination under human rights law might provide a parallel experience on how, conceptually, it might be possible to reconcile development objectives requiring positive discrimination with the overall objectives of MFN and national treatment – that trade openness might still be achieved without resort to the level playing field of unequal players.

2.4 A limitation to 'trade-offs'

The fourth original aspect of the HRIA framework is that HRIAs limit the extent to which 'trade-offs' between trade reform and social impacts are possible by setting a minimum social protection floor that trade policies must respect. Trade theory has tended to focus on aggregate social welfare, accepting 'trade-offs' of minority interests in favour of overall benefits to the majority. HRIAs challenge the view that there have to be both winners and losers from trade liberalization and that 'one has to break a few

eggs to make an omelet'.[18] If trade reform were to lead to long term unemployment in sectors with little hope of transfer to alternative employment, or significantly threaten food security, or dislocate rural communities, or fail to protect the cultural rights of indigenous communities, then an HRIA might draw on human rights standards as an indication of where to limit the extent or direction of trade reforms.

Generally speaking, HRIAs challenge the notion of 'winners' and 'losers' in reform processes and necessarily focus on the potential 'losers', refusing to accept loss as inevitable. The question arises as to what extent human rights standards provide any clear limit to 'trade-offs' between individuals and the common good. On the one hand, the 'negative rights' aspects of human rights involving obligations on States and others to refrain from certain acts do provide a good means of limiting 'trade-offs'. To give an example outside the specific area of trade reform, freedom from torture provides a guide to the 'limits' of security policy. A security policy is unjustifiable if it relies on torturing prisoners. Policy-makers therefore have to consider alternative policies that achieve human security without resort to torture. Thus, if an economic modelling exercise revealed the likelihood that trade reforms might force wages below the minimum wage standard, then the human rights protection to 'fair wages' and to 'a decent living' could act as a red flag to rethink a negotiating position.[19]

However, many aspects of trade policy involve the 'positive rights' elements of human rights – entitlements to equality, to essential medicines, to adequate food, to an adequate standard of living, to free primary education and so on. Using these entitlements as a benchmark to identify the 'limits' of trade policy might prove difficult given that such entitlements are not always easily defined with any precision. For example, the standard of 'adequate food' changes quite radically from one country to the next, as does an 'adequate standard of living'. This makes them difficult to assert as a benchmark against which to limit trade policies. The Committee on Economic, Social and Cultural Rights has relied on the notion of 'core obligations' and 'minimum core content' which could provide a guide. For example, a core obligation on the right to health is to ensure access to essential medicines as defined by the WHO Essential Medicines List.[20] The List is identifiable and therefore can be used as a measure. If it could be demonstrated that a trade policy threatened universal access to the medicines on this list, this could indicate a limit to trade policy. In the Costa Rican case study, the Constitutional Court highlighted the imperative of the government

18 The quote, while originally coming from elsewhere and used in a different context, has been taken from the cover of a World Bank publication and is: 'A successful regional integration is an omelet that cannot be made without breaking eggs' in World Bank, *Trade Blocs*, Policy Research Report, August 2000 quoted in Lizano, E., and A. González, *El Tratado de Libre Comercio entre el istmo Centroamericano y los Estados Unidos de America: Oportunidades, Desafíos y Riesgos*, Banco Interamericano de Desarollo y Instituto para la Integración de America Latina y el Caribe, Washington D.C., USA, 2003, p. 1.

19 ICESCR, Article 7(a)(i) and (ii).

20 United Nations, 'The Right to the Highest Attainable Standard of Health', General Comment 14, Committee on Economic, Social and Cultural Rights, (E/C.12/2000/4: para. 43).

protecting universal access to essential medicines in the context of CAFTA. While the Court did not use the right to health to impose a limit on trade-policies as such, it did use the right as a benchmark to ensure that, whatever policy options the Government chose, it had to continue guaranteeing universal access to essential medicines. In other words, avoid a 'trade-off' between intellectual property protection and health that threatened the right to health.

However, other aspects of 'core obligations' are less clearly defined. The Committee has identified the 'minimum core obligation' to 'ensure the satisfaction of, the very least, minimum essential levels of each of the rights' in the Covenant such as 'essential foods stuffs, of essential primary health care, of basic shelter and housing, or the most basic forms of education'.[21] Ultimately, this is not stating much more than what is already covered in the Covenant and would not provide much guidance in setting limits to trade policy. Of course, the Committee's reticence to go further is also a reflection of the importance of national conditions in defining what 'essential foods stuffs' or 'basic shelter and housing' are. If these are more clearly defined nationally, then this could provide a clearer guide to HRIAs as to what are the minimum levels of human rights protections that trade policy must respect. Such an example might be where the State has already introduced an affirmative action scheme in favour of indigenous businesses or organizations run by persons with disabilities. If an HRIA were to indicate that government procurement reforms in a trade agreement were to threaten such affirmative action schemes, the HRIA could identify continuation of the affirmative action scheme as a limit of the trade policy and recommend either that the negotiations do not include such reforms or that appropriate protections are included in the agreement to preserve such schemes.[22] Consequently, HRIAs could help identify the limits to trade agreements, although their capacity to do so will differ between rights as well as in relation to the level of existing protections to human rights at the national level.

2.5 Legal accountability

The fifth original aspect is that HRIAs turn social imperatives into legal rights and obligations, giving greater force to the recommendations of an assessment. Civil society organizations have criticized the European Commission's TSIAs on the basis that negotiators do not implement recommendations systematically, there is no way to challenge the accuracy of recommendations, nor is there a mechanism to ensure that

21 United Nations, 'The Nature of States' Parties Obligations: Article 2, paragraph 1 of the Covenant', Committee on Economic, Social and Cultural Rights, General Comment No. 3, (para. 10).

22 This already occurs to a certain extent. For example, CAFTA, Article 9.14.1.d, 'Exceptions', states that nothing in the Chapter on Government Procurement may be construed to prevent a party from adopting or maintaining measures 'relating to goods or services of handicapped persons, of philanthropic organizations'. Of course, an HRIA would propose to go further and include such schemes seeking substantive equality for people identifying with any category of discrimination.

negotiators take recommendations into account.[23] By casting recommendations in a legal framework, an HRIA offers the opportunity of strengthening the accountability of trade negotiators and other actors. Indeed, trade negotiators could potentially use this to their advantage, relying on the States' legal responsibilities to respect human rights as a means of setting a bottom line to negotiating positions when faced with a persistent and stronger trade negotiator. Unfortunately, while such an option sounds hopeful in theory, it might not always play out in reality. When Costa Rican negotiators raised their human rights obligations, including the right to health, with the US during the process of negotiating the CAFTA, the US responded that the negotiations were a commercial matter and unrelated to human rights. Consequently, in this case at least, when faced with a persistent and stronger trade negotiator, human rights arguments had little – indeed, no – effect.[24]

Nonetheless, the legal framework underlying human rights law does offer a means of protecting the rights of persons who might suffer negative impacts as a result of trade reforms. Indeed, the very value of defining basic needs in terms of 'rights' is that the basic need becomes an enforceable entitlement. The Costa Rican case study provides an interesting example. The recognition of the justiciability of the right to health through the grant of the *amparo* remedy indicates an avenue to ensure that the right to health is protected in the context of trade. The responsiveness of the Constitutional Court to grant the remedy provides a good indication that the right to health should be protected whatever the outcome of the implementation of the TRIPS plus provisions in CAFTA. Indeed, the Constitutional Court made this clear in its Advisory Opinion on the constitutionality of CAFTA when it determined that, whatever the impact of the intellectual property provisions on access to medicines, the Government was under an obligation to ensure universal access to medicines.[25] The legal enforceability of the right to health has the potential to act as a buffer to possible negative impacts of CAFTA on access to essential medicines.

It is important to highlight several provisos to this claim which prevent the conclusion that the legal accountability underlying HRIAs will have a significant effect in all cases. While the Costa Rican case study demonstrates the legal potential of human rights, this might not be applicable in every assessment or country. Importantly, Costa Rica has four important elements which qualify as pre-conditions to human rights acting as an effective accountability framework: first, legal recognition of all human rights, including those rights more affected by trade agreements such as the right to health; second, recognized justiciability of all rights; third, a functioning and independent legal system; and, fourth an active civil society conversant in human rights. Without these four pre-conditions, the usefulness of human rights as a means of strengthening the accountability of key actors might diminish. Nonetheless, this

23 FIDH, *op.cit.*, 12; European CSO Statement, *op.cit.*, pp. 2f.

24 Discussions with Susana Vásquez, Ministry of External Trade (COMEX), Costa Rica, 4 November 2008.

25 Sala Constitucional de la Corte Suprema de la Justicia, Resolución 2007-09469, 3 July 2007.

suggests a strong potential for the human rights framework to protect individuals in the context of trade agreements, which helps to reinforce the value of HRIAs as a tool to assess trade agreements.

2.6 A supportive network of actors

Sixth, HRIAs draw on human rights institutions and networks that can help to bring about transformative change. Institutions include UN and regional human rights mechanisms such as regional courts, treaty bodies and special procedures of the Human Rights Council, intergovernmental organizations such as the Council of Europe or the Office of the High Commissioner for Human Rights, international human rights NGOs such as Amnesty International, Human Rights Watch, or 3D Trade, Human Rights and Equitable Economy (which specializes in the area of human rights and trade), networks such has ESCR-Net, networks of national human rights institutions, and so on. Of course, the value of international mechanisms should not be overstated. The UN, regional and national human rights mechanisms have a heavy agenda and varying potential to affect national policy-making. Human rights NGOs also have a full agenda and the question of the impact of trade agreements on human rights might not be a priority. Moreover, the stronger enforcement of trade agreements could counterbalance the effectiveness of human rights mechanisms, often based on mediation and persuasion rather than legal enforceability, in the event of disputes arising.

Nonetheless, human rights institutions do have a role to play in monitoring human rights in the context of trade reforms and HRIAs could provide a means to involve these actors both in follow-up to an assessment, as well as in more general discussions on protecting human rights in the context of trade. The fact that the national human rights institutions of Thailand and Costa Rica have been the first to undertake human rights impact assessments of trade agreements illustrates the potential for human rights mechanisms to be directly involved in HRIAs. International civil society organizations have been instrumental in bringing *amicus briefs* raising human rights concerns before international investment tribunals[26] and in raising trade concerns before human rights bodies.[27] Special procedures of the Human Rights Council have undertaken two missions to the WTO and are increasingly monitoring impacts of trade on human rights. While the effectiveness of these efforts has to be examined on a case-by-case

26 See e.g.: *Biwater Gauff (Tanzania) Ltd v United Republic of Tanzania*, International Centre for Settlement of Investment Disputes, Procedural Order Number 5 allowing an *amicus brief* referring to the human right to water to be brought in the proceedings by: The Lawyers' Environmental Action Team, The Legal and Human Rights Centre, The Tanzanian Gender Networking Programme, the Center for International Environmental Law and the International Institute for Sustainable Development.

27 The organization 3D Trade, Human Rights, Equitable Economy has been active in raising trade issues with the Committee on Economic, Social and Cultural Rights and the Committee on the Rights of the Child (see further: http://www.3dthree.org/en/pages.php?IDcat=4 – accessed 22 January 2009).

basis, the existence of a transnational network of intergovernmental, non-governmental and expert human rights mechanisms and organizations is an important characteristic of the international human rights regime and provides a fairly unique opportunity to involve a network of actors to strengthen the follow-up to HRIAs. On the other hand, over-reliance on human rights mechanisms to highlight the impact of trade agreements might have the effect of concentrating discussions on HRIAs in human rights mechanisms and away from trade processes where decisions on trade policy are made. This could side-line HRIAs and limit their role to one of advocacy rather than promoting HRIAs as a stimulus for change from within.

2.7 Conclusions

In conclusion, HRIAs do offer some benefits which go above and beyond other impact assessment frameworks for analysis of trade agreements. The comprehensive and legal analytical framework of HRIAs offers a means to broaden and deepen impact analysis of trade agreements, limit trade-offs (to some extent) between trade openness and peoples' lives, stimulate conceptual thinking about our trading system, and promote greater legal accountability of key actors in trade policy-making. However, these benefits might not always arise in all cases. Moreover, the benefits of HRIAs to analysis of trade agreements should not be over-stated. Significantly, the extent to which HRIAs are able to identify new options for trade policies might be somewhat limited.

3 Risks of Human Rights Impact Assessments of trade agreements

3.1 Politicization

The first, and possibly most significant, risk from HRIAs is the potential of the human rights framework to politicize the impact assessment process. The term 'politicization' is used to refer to the tendency for certain issues to become particularly sensitive, which can have the effect of polarizing debates and shifting the focus of a discussion from the problem at hand towards other issues, such as avoiding criticism or protecting certain political or powerful interests. It is difficult to escape the link between politics and human rights, thus adopting a human rights framework to impact assessment has to come to terms with this. The human rights framework necessarily politicizes actors. Individuals and groups who might not be part of the majority are empowered. Representatives of government or corporations become more than partners in the assessment process; they are visible actors with legal and moral responsibilities – the human rights framework can threaten arbitrary powers of civil servants and expose corporate policies as human rights violations. An examination of health policy from a human rights perspective can take on a new, and potentially threatening, perspective. The 'politicization' resulting from human rights need not automatically be a bad thing. However, here the term is used in a negative sense: in other words, the human rights

framework might 'politicize' the assessment process by distancing some partners who might otherwise have participated in the assessment process, and moreover, lead to actors manipulating the results of an HRIA to avoid ends that might be unfavourable to them. Depending on how this threat of 'politicization' is handled, assessment partners might be more or less willing either to undertake or to participate in an impact assessment which, in turn, could have a significant impact on the quality and usefulness of an HRIA.

An important factor that could determine whether the risk of politicization overrides the benefits of undertaking an HRIA is whether a culture of human rights exists in the country under consideration. Consider the example of China. The United Nations Environmental Programme has undertaken two Integrated Impact Assessments of the impact of trade openness in China, both of which included an assessment of social impact, indicating a willingness of the Government and other actors to consider social impacts of trade agreements openly.[28] However, when Rights and Democracy undertook an HRIA of corporate investments in Tibet, the political and security situation prevented the use of human rights terminology during the assessment.[29] The openness to analyze social impacts was not matched by an openness to consider human rights impacts. This is of course an extreme example given the highly sensitive situation currently existing in Tibet. Yet in countries where a culture of human rights does not exist or worse, where the notion of human rights is strongly contested, the effectiveness of a human rights framework for impact assessment might be considerably weakened. In not referring to human rights explicitly, there is a risk that the benefits of the human rights framework recede as the HRIA appears increasingly like social impact assessment.

However, politicization need not always arise. To give a counter example, the issue of politicization did not arise in any significant way during the Costa Rica case study. Indeed, representatives of all government departments were very open in acknowledging the existence of a right to health as well as the responsibilities of the State to respect this right. Consequently, the threat of politicization should not be over-emphasized or at least assumed in every case. The human rights framework naturally gives rise to tensions between rights-holders and duty-bearers but this is not a reason in itself to avoid a human rights framework. Indeed, the threat of politicization should be balanced by the potential of the human rights framework to empower individuals. Again, taking an example from the Costa Rica experience, in 1997 the Constitutional

28 United Nations, *Integrated Assessment of the Impact of Trade Liberalization on the Rice Sector*, UNEP Country Projects Round III, A Synthesis Report, United Nations Environment Programme, New York and Geneva, 2005; United Nations, *Integrated Assessment of Trade Liberalization and Trade-Related Policies*, UNEP Country Projects – Round II, A Synthesis Report, United Nations Environmental Programme, New York and Geneva, 2002.

29 Rights and Democracy, *Human Rights Impact Assessments for Foreign Investment Projects: Learning from Community Experiences in the Philippines, Tibet, the Democratic Republic of Congo, Argentina, and Peru*, International Centre for Human Rights and Democratic Development, 2007, p. 26.

Court forced an unwilling government to supply anti-retrovirals to people with HIV/AIDS free of charge. Discussions during the case study indicated that government representatives were unwilling and even hostile to the idea at the time. Today, Costa Rica has a successful HIV/AIDS programme including free provision of anti-retrovirals, a fact acknowledged and welcomed by Government actors.[30]

Ultimately, the risk of politicization must be considered on a case-by-case basis. The existence of a culture of respect for human rights is a critical factor in determining whether politicization might outweigh the benefits of relying on a human rights framework for assessment. The risk of politicization might also change depending on which actor undertakes the HRIA. For example, national human rights institutions, as independent mechanisms appointed though government, could help to depoliticize the HRIA process where the government respects the institution and its work. Civil society organizations might be more open to the political nature of the HRIAs framework and might consider it an advantage to promote lobbzing efforts.

3.2 Annexation

Second, while this dissertation has relied upon a progressive understanding of human rights, based on UN instruments, other actors use the term human rights in varying and potentially quite opposing ways. This could not only diminish the rigour of a human rights analysis and weaken the results of an assessment, but also lead to the annexation or appropriation of those results for quite different ends. For example, while HRIAs use the human rights framework as a means of questioning the trade regime, other commentators have used human rights discourse to argue that trade rules have constitutional functions akin to human rights, potentially using human rights to hold the current view of free trade above challenge.[31] As Alston has stated, this approach is at best problematic from the perspective of international human rights law and, at its worst, would dramatically undermine it.[32] In a similar vein, some commentators have argued that the TRIPS and health debate has raised an issue of competing human rights, between patent rights and the right to health, which would undermine the approach identified in this HRIA methodology and would seek to protect individuals fundamental right to health in the face of strong protections for corporate-held patents.[33] The situation might arise whereby the results of a human rights impact

30 Discussions with Richard Stern, 28 November 2008. See e.g.: Ministerio de Salud, Consejo Nacional de Atención Integral al VIH y Sida, CONASIDA, Comisión Nacional de Monitereo y Evaluación, 'Informe Nacional sobre los Progresos Realizados en la Aplicación del UNGASS', Seguimiento de la Declaración de Compromisos sobre el VIH y Sida, Costa Rica 2006-2007, Report to the General Assembly, January 2008.

31 See the discussion in Chapter 3.

32 Alston, P., 'Resisting the Merger and Acquisition of Human Rights by Trade Law: A Reply to Petersmann', *European Journal of International Law,* 13(4), 2002, 815-844.

33 Walker, S., 'A Human Rights Approach to the WTO's TRIPS Agreements', in Abbott, Breining-Kaufmann and Cottier, *op.cit.*, 171-179.

assessment indicating potential negative impacts of a trade agreement on human rights could be justified on the basis that the trade agreement was promoting other 'human rights', namely to free trade.

Human rights might also be annexed or misappropriated in a less direct way, albeit with similar consequences, where human rights and trade liberalization are included on the same agenda uncritically as if they were entirely complementary. The Economic Partnership Agreements and Association Agreements of the European Union provide an example. These agreements generally include three pillars covering Political Dialogue, Cooperation and Trade. The Political Dialogue and Cooperation pillars include issues such as democracy and human rights, justice and liberty and social cohesion, while the Trade pillar includes market access, intellectual property protection and other areas subject to trade rules.[34] The combination of human rights and trade on the same agenda but under separate pillars not only risks concealing potential tensions, it suggests that the two areas are separable and distinct while at the same time consistent and complementary, a contention that might well be contestable. As Nwobike notes, the European Union's insistence on reciprocity in Economic Partnership Agreements with the ACP countries potentially threatens, rather than complements, the enjoyment of human rights.[35] This might give the impression that promoting human rights is akin to current forms of trade reforms, and thus devalue the potential for HRIAs to critique trade rules.

The potential for annexation of human rights exists but it might not always be present. None of the participants during the Costa Rican case study, including industry representatives, made the claim that strengthened protections for patents and test data were in some way connected to the protection of human rights. The Advisory Opinion of the Constitutional Court did observe that authors' rights were Constitutional rights, the protection of which had to be balanced with the 'fundamental' right to health, although this did not alter the Court's conclusion that the Government had an obligation to respect the right to health in the context of strengthened intellectual property protection under CAFTA.[36] Moreover, where there is a risk of annexation, a well-executed HRIA should help to clarify rather than obscure both the definition and the value of the human rights framework to analyzing trade agreements.

34 See e.g.: the Partnership Agreement Between the Members of the African, Caribbean, and Pacific Group of States of the One Part and the European Community and its Members, of the Other Part, Signed in Cotonou, 23 June 2000 and its Amendment (available at: http://www.acpsec.org/en/treaties.htm – accessed 22 January 2009).

35 Nwobike, J.C., 'The Emerging Trade Regime Under the Cotonou Partnership Agreement: Its Human Rights Implications', *Journal of World Trade*, 40(2), 2006, 291-314.

36 Sala Constitucional de la Corte Suprema de la Justicia, Resolución 2007-09469, 3 July 2007.

3.3 Externalization

A third risk related to the human rights framework is that framing trade-related social concerns as human rights concerns could externalize them from the trade regime by making them 'human rights concerns' and *ipso facto* 'non-trade concerns'. The fact that they are 'human rights concerns' is of course clear. However, defining them as such and mobilizing actors such as human rights treaty bodies and civil society organizations which are not directly involved in trade-policy debates could have the opposite effect of defining them as 'somebody else's problem'. This not only conceals an implicit definition of what *is* a trade concern (why after all is intellectual property protection a trade concern?), it also makes it easier to maintain social aspects of trade on the periphery of the trade agenda. Thus, the debate shifts from *how* the trade regime can meet its own social objectives to *whether* the trade regime can or should take into account external social concerns (defined as human rights concerns) and if so, *how much* the trade regime should taken them into account. The trade regime and its underlying purpose remains unquestioned and, potentially, unchangeable. At best, social concerns might prevail but they might loose out, and at no apparent cost to the trade regime. Consequently, while the human rights framework seeks to place the promotion and protection of human rights at the heart of the purpose of the trade regime, a human rights framework might in fact have the opposite effect, instead defining itself and its concerns out of the equation.

If HRIAs of trade agreements in fact distance social concerns from the trade agenda, the result is clearly unsatisfactory. This tends to work against the potential for HRIAs to act as a stimulus for change. One factor militating against this occurring is that an HRIA deals with concrete cause-effect relationships between trade reforms and the enjoyment of human rights. This evidence-based approach to analysis distinguishes it from the more abstract discussions on fragmentation of international law which have concentrated on the interplay between norms, rather than on questions of evidence, causal relationships and impact. This focus on cause-effect relationships should help not only make the relationship between trade agreements and impacts on people clearer, it should also help place social concerns closer to the centre of the trade regime. Another way to avoid this externalization of the results of HRIAs is to imagine ways to link them to trade mechanisms and trade thinking. HRIAs could be promoted as a way of giving substance to Pascal Lamy's call for a 'Geneva Consensus' that seeks a more human trading regime. Similarly, strategies involving human rights bodies and organizations as a means of raising the results of HRIAs could be matched with strategies to raise results in trade monitoring for a, such as in the WTO's Trade Policy Review Mechanism.

3.4 Imbalance

Fourth, a common problem of the human rights framework is that it focuses on the cases of human rights abuse and potentially loses sight of the positive changes that

might occur in society through trade. As noted in Chapter II Section 3, relatively little human rights critique of the trade regime focuses on its positive elements. This is almost a natural consequence of a human rights analysis which focuses more closely on avoiding and remedying human rights violations and focusing on those individuals often left out of policy-making. Yet, evidence that trade openness has had positive impacts is also important. The risk in placing such a strong emphasis on the 'losers' of trade liberalization is that an HRIA might focus attention too quickly on the option of trade protectionism (which also poses risks including to human rights), passing over the option of using HRIAs as a means of examining what sort of open trade regime is appropriate or desirable. Such a risk is often present when relying on a human rights framework. Consequently, it is important that assessors report positive as well as negative impacts of trade agreements, not as a means of justifying negative impacts in a trade-off with positive impacts, but rather as a means of contextualizing impacts and ensuring that not only are the rights of individuals in vulnerable situations not left behind in trade policy-making but also that the benefits of trade reforms are not sacrificed unnecessarily. This should focus an HRIA less on debating the virtues of trade openness and more on the analysis of the impact of the policies designed to achieve trade openness.

3.5 Feasibility

An additional factor affecting the added-value of HRIAs is their feasibility. In particular, HRIAs face challenges of time, budget, expertise and data which make them relatively onerous to perform. This dissertation has illustrated the range of trade agreements that have the potential to affect human rights, the range of different people and institutions affected, and the variety of rights concerned. Ideally, an HRIA should consider the potential effects of all relevant trade agreements on all related rights, which is clearly a mammoth task. In addition, the emphasis on participation and participatory techniques can be significantly onerous in terms of time and resources. This all requires time, a range of expertise including at least an economist, a lawyer and a social scientist, as well as an appropriately sized budget to cover costs related to consultancy fees, travel and so on. The data requirements in considering the impact of a range of sectors could be considerably onerous, particularly in countries where reliable primary data does not exist, or exists partially, and so the assessors have to gather data themselves. Of course, some of these challenges also face other impact assessment frameworks, such as social impact assessments or sustainable impact assessments. However, the comprehensive nature of the HRIA framework, particularly with its focus on participation, could limit the ways that costs could be reduced.

The Costa Rica case study, although only a limited study, provides an illustration of the sort of time, budget, expertise and data requirements of an *ex ante* HRIA of a trade agreement. In terms of time, the case study took the equivalent of three months full-time work – this includes all stages from preparation and screening stages, to one month's full time work on the case study in Costa Rica, and then the drafting of the

final report, although it leaves out the additional time allotted for participants to provide comments. Moreover, the three months does not include the time taken for the Partial Equilibrium Model, which was undertaken independently by another organization prior to the case study period. Undertaking a full assessment would take considerably more time, potentially between six months and one year, as it should also have considered market access in relation to agricultural trade, other aspects of intellectual property protection, in particular ratification of UPOV, impact of CAFTA on employment and workers' rights, and the impact of chapters on investment and trade in services on universal access to essential services. Budget issues were limited to travel and accommodation costs for one month in Costa Rica, although for a full assessment it would be necessary to factor in consultancy fees as well as travel for at least three experts. It has to be noted that similar budget issues would have faced an impact assessment not relying on a human rights framework.

In terms of data collection, a significant amount of data was already available for the case study given the high level of interest in Costa Rica on the impact of CAFTA. Moreover, the government maintains and makes publicly accessible considerable data and statistics comparing favourably with other countries, particularly in the region.[37] Another issue which helped with the Costa Rican case study at the level of data collection was that participants were easily approachable and willing to take part in the case study. The prevailing human rights culture in the country no doubt made it easier to approach and to engage participants. Indeed, the problem facing data collection was not a lack of data, but rather a lack of time to examine all the available data closely. However, the data collection process could have been considerably more burdensome than it was. First, given the existence of both a solid public health system as well as good health data, it was possible to conclude that there was an effective system of universal provision of essential medicines. The universal nature of the system made it easier to avoid having to disaggregate data (given that the provision was universal). This is not to state that there might not have been discrimination in practice, but that, for the purposes of the assessment, it was possible to conclude that, as a baseline, Costa Rica had in place an effective access to medicines regime. However, had the baseline not indicated universal access, then the baseline study would also have had to examine whether people in any of the protected categories were suffering disproportionately from the lack of access. This would have made the case study particularly laborious.

Second, the focus on access to medicines meant that it was less important to rely on participatory assessment techniques. The existence of a high level of enjoyment of the right to health in Costa Rica already meant that there was less relevance to gathering data on individual experiences. The case study could have gathered data on

37 Discussion with a representative of the International Centre for Trade and Sustainable Development noting that the Partial Equilibrium Model had been easier to perform in Costa Rica than in the Dominican Republic precisely due to the effective maintenance of records in Costa Rica – September 2008.

individuals' experiences of the current access to medicines regime and their fears related to the intellectual property protections threatening universal access; however, the question arises whether that data would have added much to the analysis. For example, the views and opinions of 'rights-holders' were less relevant to this assessment than an analysis of the institutional framework supporting access to medicines in Costa Rica. This was due to the fact that the institutional framework had the most significant role in avoiding negative impacts on the right to health. In contrast, if the case study had focused on liberalization of agricultural trade and its impact on the right to an adequate standard of living of rural communities and small farmers, the importance of including participatory techniques would have been considerably more significant. This in turn would have increased the burden of data collection considerably. This of course would have raised the question of how to identify the appropriate number of participants in the case study to avoid overly subjective data that could be relevant to a national HRIA. This, in turn, would put even greater time pressure on the HRIA.

A number of other challenges arose at the level of data collection and analysis. The case study notes three main data collection and analysis techniques, namely the Partial Equilibrium Model, causal-chain analysis and expert opinion. The importance of expert opinion to this or any case study underlines the ultimately subjective nature of HRIAs. While economic modelling and the use of causal-chain analysis (or rather sound legal reasoning), together with the implementation of a clear methodology, all help to provide a level of objectivity to the analysis, there is nonetheless a significant level of judgment involved in identifying what information to refer to, as well as how and where to refer to it. Moreover, although the use of key informants was an important means of improving the 'expertise' of the expert opinion, the use of key informants really depended on the level of trust the assessor had in the key informant. For example, some of the government key informants appeared to be placing a significantly positive gloss on the likely impact of the intellectual property provisions on access to medicines. It was difficult to assess the extent to which some opinions were sincerely held, and which opinions reflected the key informant's role as a civil servant.

There are several interviewing techniques that can assist in exposing bias or challenging interviewees who might be covering up details. Including several interviewees from the same department can also help to expose inconsistencies, although this again adds to the burden of impact assessment. It has to be underlined that these challenges to data collection and analysis face other impact assessment frameworks relying on key informants and expert opinion. However, the political nature of HRIAs might place additional pressure on certain key informants, such as government actors, to avoid voicing certain opinions or to cover up certain evidence for fear of the legal and related repercussions.

3.6 Conclusion

In conclusion, although HRIAs bring certain benefits to impact analysis of trade agreements, there are also some risks associated with the human rights framework. The risk of politicization could make some actors less willing to undertake or participate in an HRIA. The use of a human rights framework might lead to confusion and even annexation by actors more interested in consolidating current notions of trade openness and market freedoms than in seriously considering the impact of trade agreements on peoples' lives. A human rights framework might have a tendency to focus too heavily on negative impacts of trade agreements and so polarize debates, potentially losing sight of the beneficial aspects of trade openness while at the same time externalizing critiques of trade agreements making the human impact of trade agreements 'somebody else's problem'. Finally, the comprehensive nature of the human rights framework could prove to be onerous in terms of time, budget, expertise and data if the framework is applied fully. The eventual impact of these issues on the effectiveness of HRIAs will differ from case to case. Several factors could influence their impact including: the existence of or emergence of a culture of human rights; the entity – government, NGO, national human rights institution, academic institution – undertaking the assessment; the strength of the arguments used to demonstrate the cause-effect relationships between trade and the enjoyment of human rights; and, the extent to which HRIAs can be linked to trade mechanisms and institutions so as to stimulate changes from within the trading regime.

FINAL OBSERVATIONS

It is now possible to return to the research question underlying this study:

Is there value in undertaking HRIAs of trade agreements in a more systematic manner?

In order to answer this question, it will be remembered that answers to two initial questions would be necessary:

1. *What benefits do HRIAs offer to the assessment of trade agreements?*
2. *What are the risks involved in undertaking HRIAs?*

The proposal to undertake HRIAs of trade agreements has arisen out of the need to negotiate and implement trade agreements in ways that take into account more explicitly their human dimensions. However, the proposal must be placed within a larger context of economic, social and environmental impact assessments of trade agreements, discussion of which has been ongoing for some decades. To the extent that these existing impact assessment methodologies, in particular social impact assessments of trade agreements, already examine the human dimensions of trade agreements, HRIAs must make the case that they offer something above and beyond other impact assessment methodologies if we are to proceed further and test the methodology and encourage States and other actors to undertake HRIAs more systematically.

Before providing some answers to the research question, it is important to note that any exercise, undertaken seriously, to collect information on the real or likely impacts of trade agreements certainly has a level of inherent value. HRIAs provide information about the impact of policies that affect all of us and focus on those often left out of policy-making processes. HRIAs help us to learn about trade, deepen our understanding of its effects and, ideally, make better policies for the future. At one level therefore, it is possible to argue that the more methodologies that are available to assess the impact of trade agreements, the better. The issue becomes almost one of preference. Lawyers might prefer using a human rights framework, with its emphasis on legal principles, norms, standards, and accountability mechanisms. Similarly, grass roots campaigners might find the moral authority of human rights language forceful for lobbying efforts and applying pressure to policy-makers. Others might instead seek to test economic theories or identify positive outcomes on the macro-economy and might wish to avoid the potentially abrasive language of 'rights' and 'obligations' and thus

prefer to rely on another impact assessment methodology such as integrated impact assessment. In this sense, HRIAs line up with other impact assessment methodologies, providing yet another option.

HRIAs also should provide human rights professionals and human rights mechanisms with information relevant to the functioning of the human rights system. For example, HRIAs should provide information and analysis on trade impacts which can help to inform human rights mechanisms such as courts, treaty bodies, special rapporteurs, political bodies such as the Human Rights Council, and others about the relevance of trade agreements for their work. As already noted, some UN treaty bodies such as the Committee on Economic, Social and Cultural Rights and the Committee on the Rights of the Child have held days of general discussion on the impact of trade agreements on their respective treaties and have included the topic of trade agreements in their constructive dialogue with States. HRIAs should help provide additional information, analyzed within a human rights framework, to deepen treaty body discussions on treaty implementation. Special procedures such as the Special Rapporteur on the Right to Health and the Special Rapporteur on the Right to Food have already undertaken missions to the WTO and the HRIA methodology developed in the present study might assist them in undertaking trade-focused country missions in the future. HRIAs might also provide information for inclusion in the various reports of the new Universal Periodic Review mechanism of the Human Rights Council.

Importantly, HRIAs of trade agreements could help deepen our understanding of the economics of human rights. The traditional focus of human rights bodies and experts on civil and political rights and on violations has tended to pass over the economic issues relevant to providing the resources to promote human rights. The focus of the human rights system on the abuse of individual journalists, prisoners, individuals in psychiatric institutions, political dissidents, individuals who suffer discrimination, and so on, has tended to concentrate human rights work more on relieving individual suffering, which, although this is a fundamental issue for human rights work, also risks passing over the broader economic context and the importance of positive duties on States that can be a significant factor in avoiding many human rights violations.[1] HRIAs of trade agreements should help rebalance human rights discussions with a deeper understanding of how trade can be channelled in ways to meet States positive human rights duties – to realize progressively economic, social and cultural rights and to ensure civil and political rights.

Moreover, while HRIAs of trade agreements primarily focus on ways that trade reforms affect human rights, an off-shoot of this process could also be to deepen

1 The point of course should not be made too crudely. It cannot be overlooked that the human rights system has traditionally focused on the underlying biases that lead to human rights violations – the obligation in CEDAW to undertake temporary special measures being a good example – but the renewed interest in economic, social and cultural rights places a greater or renewed emphasis on the positive duties on States to create the economic and other conditions conducive to the full enjoyment of human rights.

understanding of the human rights framework, how that framework might have to adapt, both normatively and in practice, to the objective of making trade work for people, and how trade can be an important engine for the promotion of human rights. If HRIAs are undertaken in a more systematic manner by human rights practitioners, they might provide sufficient evidence to suggest a clarification of human rights norms in the context of trade. Simply put, experience might help identify where the normative content of rights needs greater specificity, which in turn might provide a springboard for legal reform.[2]

These factors all add up to suggest that there certainly appears to be some 'value' in progressing further with HRIAs of trade agreements, at least as a tool to progress discussions *within* human rights fora. However, this does not answer the question fully as HRIAs also have the objective of transforming trade agreements which requires going *beyond* the limited arena of human rights fora. Is there value in progressing to the next stage of testing the HRIA methodology in light of the fact that there are already impact assessment methodologies that consider the human dimensions of trade agreements? In order to answer the research question posed in the Introduction, this thesis has developed a methodology for *ex ante* human rights impact assessments of trade agreements and provided an illustration of what this looks like in practice. The methodology consists of a human rights framework or approach to impact assessment, an identification of the original aspects of the human rights framework compared to social impact assessment frameworks, a categorization of potential impacts of trade agreements on human rights, a step-by-step process for undertaking assessments, a method to develop reliable and valid human rights indicators as impact measurements, and a review of relevant data collection and analysis techniques. The methodology has been illustrated through a study of the impacts of CAFTA on human rights in Costa Rica.

On this basis, Chapter IV has considered the benefits offered by the human rights framework to the specific issue of analyzing the impact of trade agreements. The norms and standards of human rights law provide a framework that permits a broader and deeper analysis of the impacts of trade agreements. It helps to empower indi-

2 The Convention on the Rights of Persons with Disabilities (CRPD) provides an interesting parallel in this regard. The particular experience of persons with disabilities experiencing difficulty accessing cultural materials protected by intellectual property rights led to the inclusion of a specific article on the issue. CRPD, Article 30(3) states: 'States parties shall take appropriate steps, in accordance with international law, to ensure that laws protecting intellectual property rights do not constitute an unreasonable or discriminatory barrier to access by persons with disabilities to cultural materials'. In parallel, discussions have recently begun in the UN's World Intellectual Property Organization (WIPO) on this issue, with the commissioning of a study on 'Copyright Limitations and Exceptions for the Visually Impaired', which makes reference to the obligations under the CRPD in this regard and proposes amendments to international intellectual property norms. See WIPO, 'Study on Copyright Limitations and Exceptions for the Visually Impaired', Standing Committee on Copyright and Related Rights, Geneva, 2006, (SCCR/15/7: p. 135) (available at: http://www.wipo.int/edocs/mdocs/copyright/en/sccr_15/sccr_15_7.doc – accessed 13 April 2009).

viduals who might otherwise be forgotten in trade policy-making, while holding States and trading enterprises responsible for their actions as they affect people. In the right conditions, HRIAs link assessment of trade agreements to justice mechanisms and international networks of human rights organizations which can add pressure and urgency to the results of assessments. While the human rights framework might not necessarily provide the answers to which trade policies should be adopted, HRIAs provide a means of questioning trade regimes, providing evidence of their effects and stimulating new ways of thinking about trade reform. The human rights framework underpinning HRIAs offers fresh perspectives on concepts common to both human rights law and trade law, such as 'free' trade and 'non-discrimination'.

Chapter IV then analyzed the risks involved in undertaking HRIAs of trade agreements. That analysis revealed that the strengths of the human rights framework can also be its weaknesses. Human rights language can be counterproductive, alienating and irritating to some key actors. While it can be unifying and empowering for individuals, it can be splintering and threatening for governments and others. While this can be potentially powerful, it can also lead to an over-politicization of human rights and the distancing of key actors, particularly governmental actors. Where a culture of human rights does not exist, the element of politicization could undermine the benefits of the human rights framework. Even where a culture of human rights exists, governments might be wary of undertaking HRIAs rather than social impact assessments, as the former could expose government actions and decisions to legal review in ways that social impact assessments might not.

Further, human rights discourse can be manipulated or appropriated to ends which would not necessarily serve the goals of the methodology developed in this thesis. This can occur when human rights discourse is used to defend current trade policies as having a constitutional or fundamental value – in this way, human rights might be used to maintain the status quo rather than act as a tool for policy critique. Similarly, where legal frameworks are inadequate, underdeveloped or inaccessible and legal norms are not sufficiently defined to provide a measureable standard, the benefits of the legal framework of human rights diminish. Moreover, the comprehensive nature of the human rights framework tends to make it quite onerous in terms of the skills, as well as the time and resources, needed to undertake HRIAs effectively. All these factors tend to moderate the benefits of the human rights framework of HRIAs.

The 'value' in undertaking HRIAs of trade agreements in a more systematic manner lies in identifying whether the benefits outweigh the risks. No single formula exists to do so. Benefits might come to the fore in some situations while in other situations risks might dominate. Determining the 'value' in moving forward on HRIAs depends in large part on minimizing the risks. For example, when considering the problem of 'externalization', it will be important to consider ways to ensure the human rights framework does not side-line social concerns as 'non-trade concerns'. The clarification through HRIAs of the cause-effect relationships between trade reforms and their impact on human rights should provide a means of reducing this risk. Submitting the results of HRIAs to trade mechanisms such as the WTO's Trade Policy

Review Mechanism might also help to place human rights concerns more squarely on the trade agenda as 'trade concerns' rather than as 'non-trade concerns'. Involving trade experts in HRIAs might not only be necessary from the perspective of feasibility of the methodology, but also a means to mainstream human rights concerns within trade thinking.

Similarly, it will be important to avoid the potential for 'imbalance' in human rights analysis. For example, it will be relevant to identify ways that HRIAs can be constructive in their assessment of trade agreements, so as not to focus only on violations which could prove to be alienating and potentially self-defeating by ignoring the benefits of trade. The inclusion of two 'impact categories' in the methodology that focus on the complementarity between trade law and human rights law and on the role of economic growth as an engine for the progressive realization of human rights might help to move away from an overly negative focus in human rights critique. Further, where negative impacts arise, HRIAs should be careful to identify constructive options to avoid those impacts in ways that can engage rather than distance trade policy-makers. Of course, these suggestions are proposed, bearing in mind the fact that HRIAs should retain a critical edge, in particular as they serve a role in bringing to the fore the situation of people who might otherwise remain invisible in policy-making processes.

Turning to the problem of 'politicization', it is probably fair to say that 'politicization' is an omnipresent threat in the context of human rights work. The power of human rights means that it offers opportunities to some and threatens the interests of others. However, 'politicization' might be less in certain situations and under certain conditions than others. In this sense, it will be important to consider who undertakes an HRIA. Civil society organizations for example might be less susceptible to the problems of 'politicization' and might see it as an advantage to help in lobbying efforts with governments. Alternatively, governments might perceive the accountability of the HRIA framework as a threat. Similarly, actors should consider ways to minimize the threat of 'politicization' by ensuring a balanced analysis, avoiding inflammatory or unsubstantiated conclusions and by guaranteeing that all actors are engaged along the assessment process so that sensitive actors feel a level of ownership in the assessment.

Another factor which could be considered in seeking to minimize the threat of 'politicization' is the location of the assessment. Where the country subject to an HRIA has a culture of human rights, the chances of 'politicization' might be reduced. For example, where government actors feel comfortable discussing human rights questions, where there are adequate human rights institutions and active civil society, human rights language might pose less of a threat. This certainly appeared to be the case in Costa Rica. Similarly, countries in transition, where a culture of human rights is emerging, might be eager to promote a positive image of themselves to the international community and therefore might consider the potential of being seen to 'do the right thing' as a beneficial factor associated with undertaking an HRIA which outweighs concerns of 'politicization'.

Perhaps one of the greatest 'risks' involved in HRIAs is their feasibility. The Costa Rican case study involved only a limited set of provisions of one chapter of one agreement, yet took three months to complete. A full assessment could take at least three professionals a year to complete and require an adequate budget to cover travel and subsistence costs as well as salaries. The requirements to seek popular participation in the assessment, as well as to ensure that the analysis complies with the rigours of the human rights framework of norms and principles, does offer on the one hand, the potential for a more thorough analysis, but on the other, it risks making the assessment unwieldy. However, the problems of feasibility have to be balanced with the benefits of having solid analysis – which has escaped some of the social impact assessments already undertaken in the field. Importantly, problems of feasibility can be dealt with by ensuring that any gaps in data and analysis are expressly clarified in the assessment report so that the assessment only concludes as much as the data justifies, no more and no less. It should also be noted that other impact assessment methodologies also face concerns of feasibility. A lack of feasibility should not alone detract from the viability of progressing further with HRIAs.

Ultimately, the benefits and risks of HRIAs will differ case-by-case. I propose that the benefits of HRIAs are more likely to come to the fore in countries which have a culture of human rights or in countries in which a culture of human rights is emerging, understood as being those countries that meet most if not all the following inter-linked criteria. First, there should be an active and open civil society which is aware of human rights standards and willing and able to engage in the assessment and follow-up on recommendations. This is important to ensure that representative non-governmental organizations are available to contribute human rights information and data to the HRIA, and to coordinate the participation of individuals in the assessment so that popular participation is as broad as possible and practicable, in line with the human rights framework underlying the assessment methodology.

Second, there should be legal protections of human rights ideally at both the constitutional and legislative levels, as well as the availability of remedies in the case of a breach of human rights. Significantly, this should mean that all rights, including cultural, economic and social rights, are justiciable, as these are the rights more likely to be affected positively and negatively by trade agreements. Legislative protection and access to remedies are important as these can act as deterrents from implementing economic policies that fail to respect human rights standards. Third, not only should all rights enjoy strong legislative protection and subsequent access to remedies, there should be functioning national institutions, including an independent judiciary, an active parliament and, preferably, a national human rights institution. Strong institutions are relevant as institutions have a role to play as participants in HRIAs as well as in following-up on recommendations of the assessment. But more importantly, strong institutions are necessary to ensure that the legislative and judicial protections identified in the second criterion are effective. Strong institutional frameworks provide a check on the various arms of government and strong human rights institutions ensure that governments are more likely to respect human rights.

Together, these three criteria indicate that a level of acceptance of human rights is present in a society which gives teeth to the human rights framework underlying HRIAs and should help to minimize at least the worst manifestations of 'politicization', such as a situation where a government decides not to participate in an HRIA merely because it is a 'human rights' impact assessment and therefore too troublesome to warrant engagement. However, without the existence of a relatively strong civil society, as well as institutional and legal frameworks, the various benefits of HRIAs might diminish, potentially leaving the associated risks more dominant or alternatively making HRIAs more difficult to distinguish from other impact assessment methodologies such as social impact assessments. The reality could well be that many countries might meet these three criteria to varying levels, leaving a level of doubt as to how effective HRIAs of trade agreements might be.

Turning to the research question, the 'value' of undertaking HRIAs in a more systematic manner depends in large part on ensuring the benefits outweigh the risks, namely through minimizing the risks and targeting countries where a culture of human rights exists or is emerging. However, the assessment of 'value' also has a subjective element and depends on the actor or actors considering undertaking an HRIA. Potential actors range from NGOs to academics, parliaments, intergovernmental organizations, national human rights institutions, trade unions and governments. Each of these actors is likely to perceive the benefits of HRIAs differently. Actors can be categorized in at least three groups, ranging from those more likely to perceive the HRIA framework as offering benefits, to those who might be less likely to be convinced.

The first group consists of human rights professionals such as human rights NGOs, national human rights institutions, academics, and actors of the regional and UN human rights systems (such as special procedures of the Human Rights Council), and inter-governmental organizations such as the Council of Europe or the Office of the High Commissioner for Human Rights. For these actors, the human rights discourse is familiar and issues such as politicization might be less relevant. Non-governmental organizations might prefer the HRIA methodology, perceiving as the risk of 'politicization' as a benefit, particularly if HRIAs are performed with a view to advance lobbying efforts or criticize key policy-makers and institutions. Special procedures or intergovernmental organizations have more experience with the politics of human rights and might be aware of ways to depoliticize the assessment process – for example, in moderating language – or alternatively, to capitalize on the political process – for example, by raising trade issues within intergovernmental fora as a means of giving greater force to recommendations.

National human rights institutions (NHRIs) are a likely candidate for undertaking such assessments. Indeed, it is not by chance that NHRIs in Thailand and Costa Rica have undertaken the two *ex ante* impact assessments of trade agreements to date. Many NHRIs have a combination of independence – which should help reduce the potential for politicization – as well as influence on governments, which should help to promote greater respect by government for any recommendations flowing from the assessment. However, many NHRIs have many competing priorities and might not always have the

human and financial resources available to confront the feasibility challenges of HRIAs, particularly institutions in developing countries. Alternatively, parliaments, through human rights committees, might see value in commissioning HRIAs as a vehicle to maintain vigilance over governments and might be less concerned about 'politicization'. It should be noted that, for this first group of actors, the problems of 'externalization' and 'imbalance' might come to the fore, particularly given that they are often far from trade negotiations and most closely associated with the human rights framework. This need not reduce the value in moving forward on HRIAs, but it will be important that these actors employ strategies, such as those discussed above, to minimize these risks.

The next group of actors consists of civil society organizations, experts, parliamentarians, academics, intergovernmental organizations and others who do not characterize themselves as human rights professionals. An example of this category would be an NGO working in the development field. Actors in this second group might see some value, albeit less value, in undertaking HRIAs. For example, they might be more familiar with social impact assessment frameworks and shy away from the human rights framework for being too sensitive or political or too technical, preferring the flexibility and ambiguity of a social impact assessment framework. On the other hand, this group might also be open to the human rights framework, particularly where the framework was perceived as a means of lobbying governments. Intergovernmental organizations not specialized in human rights, such as the United Nations Development Programme or the United Nations Environmental Programme, might be reticent to embark on an HRIA for fear of endangering their relationship with the government or on the basis that their mandates do not include the promotion and protection of human rights, or do so to a limited extent. In short, this group might be more susceptible to the problems of 'politicization', although the risks of 'externalization' might diminish given that their mandates do not place them squarely within the human rights field. Such observations are merely speculative and should be subject to testing in the future.

Finally, governments are the third group and possibly the least likely to perform HRIAs. While governments are clearly obvious candidates to undertake HRIAs, it is here that the problem of 'politicization' is probably at its greatest. Trade policies are important to economic growth and therefore sensitive for governments. Moreover, governments seek a certain level of flexibility in setting trade policies, given the give-and-take of trade negotiations. Governments are probably less likely to wish to discuss the impact of their trade policies using a framework that emphasizes their own legal accountability. An argument to encourage governments to undertake HRIAs could emphasize the importance of understanding legal accountability issues prior to adopting and implementing trade agreements, rather than dealing with such problems at a later date. However, foresight might not necessarily win the day and many governments might find a level of comfort in the social impact assessment framework.

However, governments are not an homogenous group. As noted previously, some governments, such as governments of countries in transition, might be willing to

undertake an HRIA as a means of promoting an image of a good international citizen. Poorer governments might perceive HRIAs as a way of demonstrating how a force beyond its control – namely trade policies encouraged by larger trading partners – is making their task of promoting human rights harder. Further, governments might be more willing to undertake HRIAs in other countries. For example, the European Union has supported social impact assessments of its trade agreements in partner countries and it is plausible that it might support HRIAs in the same way. An HRIA might help to meet foreign policy goals of promoting human rights abroad, make the link between human rights and trade clearer in the context of European Partnership Agreements, respond to pressure from civil society to protect human rights in the context of trade negotiations, while also reassure the government that trade agreements are meeting their own human rights obligations. However, one government undertaking an HRIA in a partner country might in turn raise political sensitivities in the second Sate, which could dampen enthusiasm to proceed with an assessment.

Assessing the 'value' of undertaking HRIAs in a more systematic manner therefore depends not only on minimizing the risks of assessment, but also on considering the perspective of the actors performing the assessment. At a minimum, human rights actors such as National Human Rights Institutions, human rights NGOs, academic institutions and special procedures of the Human Rights Council are likely to perceive 'value' in undertaking HRIAs in a more systematic manner. Other actors, including broader civil society organizations, academics, trade unions, parliamentarians, and even some governments, could also perceive 'value'. The European Union might be open to broadening their assessments of trade policies by including HRIAs.

Consequently, there does appear to be 'value' in undertaking HRIAs on a more systematic manner. This should involve first a testing of the methodology after which the question of 'value' should be reassessed. The testing of the methodology should endeavour to identify countries meeting the various conditions demonstrating that they have or are moving towards a culture of human rights, such as solid institutions, an active civil society and normative clarity and accountability. Where some or all of these conditions exist and strategies are followed to minimize risk, HRIAs offer a greater possibility to broaden and deepen analysis of trade agreements and provide a stimulus for evidence-based policy making in the field of trade in ways that build upon and go further than other impact assessments. In so doing, HRIAs should be able to help us to imagine a 'free' trade agenda that preserves the objectives of a non-discriminatory and open trading regime, and combines them with goals of promoting fairness and equality, relying on a responsible and proactive State, corporate accountability and the empowerment of the small farmers, workers, indigenous communities, people accessing essential goods and services, and others for whom trade agreements can and should work.

ANNEX 1
INTELLECTUAL PROPERTY PROTECTION IN THE TRIPS AGREEMENT RELEVANT TO ACCESS TO MEDICINES

INTRODUCTION

Costa Rica is a Member of the World Intellectual Property Organization (WIPO) and a founding Member of the World Trade Organization and is thus a Member of the Agreement on Trade-Related Aspects of Intellectual Property (the TRIPS Agreement). The TRIPS Agreement includes several provisions relevant to the protection of medicines, such as requirements to protect patents over innovations, protection of undisclosed information such as test data relating to new drugs, and protection of trade marks, including over branded medicines.

PATENTS

In relation to patents, the TRIPS Agreement requires WTO Members to protect innovations, including new pharmaceutical protects, for a period of twenty years. In order to gain protection, a pharmaceutical product, as with other innovations, must be new, involve an inventive step and be capable of industrial application. A patent over a pharmaceutical product confers the rights to prevent others from making, using, offering for sale, selling or importing for these purposes the patented pharmaceutical product.[1] In return for the grant of exclusive rights over the patented innovation for twenty years, the innovator provides a description of the innovative steps which enters the public domain for the public benefit. In this way, the grant of patents seeks to balance promotion of innovation through the grant of specific rights for a limited period, with promoting the public interest in disclosure of the details of recent innovations. Prior to the adoption of the TRIPS Agreement, Costa Rica offered only one year protection of patents over pharmaceutical products.

PARALLEL IMPORTING AND COMPULSORY LICENCES

The TRIPS Agreement also permits parallel importing and the granting of compulsory licences. Parallel importing refers to the practice of importing for sale patented products from a country where they are cheaper. Parallel importing provides a means of purchasing cheaper pharmaceutical products from another country so that the drug is more affordable in the importing country. A compulsory licence refers to a licence

1 The TRIPS Agreement, Articles 27 and 28.

granted over a patent by the Government to a third party without the authorization of the patent owner, subject to certain conditions such as non-exclusivity and non-assignability of the licence.[2] A compulsory licence provides a means of permitting a generic pharmaceutical manufacturer to produce a patented pharmaceutical product without the authorization of the patent owner so that the generic producer can supply those drugs at an affordable price. While Costa Rica does make use of parallel imports of medicines as a means of reducing the cost of drug purchases,[3] to date there has not been an application for a compulsory licence in the country.[4]

EXCEPTIONS

The TRIPS Agreement also includes several exceptions in relation to patents. WTO Members may exclude inventions from patentability for reasons of *ordre public* or morality or for the protection of human, animal or plant life or health or to avoid serious prejudice to the environment.[5] States may also provide for limited exceptions to the rights conferred by a patent so long as the exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.[6] Another exception, permitted under the TRIPS Agreement, is the Bolar Exception. The Bolar exception allows manufacturers of generic drugs to use the patented invention – the information disclosed in the patent document – to obtain marketing authorization – for example from public health authorities – without the patent owner's permission and before the patent protection expires. This enables the generic producers to market their versions as soon as the patent expires.[7]

PROTECTION OF UNDISCLOSED INFORMATION INCLUDING TEST DATA

The TRIPS Agreement potentially offers protection to test data in the form of protection of undisclosed information from unfair commercial use. In order to be protected, the test data must be 'undisclosed'. Undisclosed information must: (1) be secret in nature; (2) have commercial value as a result of the information being secret; and further, (3) the owner must have taken reasonable steps to guard the secrecy of the information. Importantly, information in the public domain is automatically excluded

2 *Ibid.*, Article 31.
3 Interview with Albin Chaves, representative of the Caja Costarricense de Seguridad Social, 12 November 2008.
4 Interview with Karen Quesada, representative of the Registro Nacional, 7 November 2008.
5 The TRIPS Agreement, Article 27.
6 *Ibid.*, Article 30.
7 Web page of the WTO (available at: http://www.wto.org – accessed 25 September 2008.

from protection as an industrial secret under the TRIPS Agreement.[8] The term 'unfair commercial use' is not defined in the Agreement.

Article 39(3) of the TRIPS Agreement provides special protection for test data related to pharmaceutical products provided as a condition of marketing authorization. First, WTO Members must protect test data over pharmaceutical products which use new chemical entities from unfair commercial use. WTO Members must protect that test data where a Member requires the test data as a condition of marketing authorization and where the test data holder has expended considerable effort in creating the test data. Second, WTO Members must protect such test data against disclosure, except where disclosure is necessary to protect the public, or unless steps are taken to protect the data from unfair commercial use.

TRADE MARKS

While less relevant for the purposes of the present case study, the TRIPS Agreement also protects any sign or combination of signs capable of distinguishing a pharmaceutical product of one pharmaceutical producer from those of another producer such as a generic producer of a similar pharmaceutical. Signs such as words including personal names, letters, numerals, figurative elements and combinations of colours as well as any combination of such signs can be protected as trade marks. The grant of trade mark protection allows the pharmaceutical producer to prevent others from using, in the course of trade, identical or similar trade marks and the rights are granted for a minimum of seven years, renewable indefinitely.[9] Trade mark protection of pharmaceutical products provides a means of avoiding consumer confusion between an original innovator product and a similar product such as a generic pharmaceutical.

8 The TRIPS Agreement, Article 39.
9 *Ibid.*, Articles 15 and 16.

ANNEX 2
INTELLECTUAL PROPERTY PROTECTION OF PHARMACEUTICALS IN PRACTICE

The following provides a step-by-step summary of the typical process of the life of a new pharmaceutical product passing through the patent process:[1]

- *Year 0* – The innovator applies patent protection in the home country;
- *Year 0* – The company begins studies into the safety and efficacy of the product with a view to obtaining marketing authorization;
- *Year 1* – Within one year of the application for patent protection in the home country, the innovator must have submitted all applications for patent protection in each country of interest to the innovator.
- *After year 1* – Once studies are complete, the company applies for marketing authorization using the information on safety and efficacy
- *Years 8-12* – It normally takes between 8 to 12 years after the initial application for patent protection to complete both the patent application process as well as the marketing authorization process in the country of origin. Around 46 percent of patent applications in developed countries are rejected.
- *After Years 8-12* – Sometime after this 8-12 year time period, the process of patent application and marketing authorization in second countries will terminate.
- *Year 20* – 20 years after the original patent application, the patent rights expire (if granted in the first place) in the country of origin.
- *Year 21* – 21 years after the original patent application, the patent rights expire (if granted) in second countries (being 20 years plus one year's grace to apply in other countries).
- *After Year 20* – Market exclusivity for the innovator company having expired, generic pharmaceutical producers can compete and competitive drug pricing replaces monopoly pricing of the pharmaceutical. However, trade mark protection continues which could allow higher prices to be charged for branded pharmaceuticals, trading on the good brand name of the original innovator producer.

As can be seen by the above, innovators have a only a limited chance of actually patenting a new drug and gaining marketing authorization and have only a portion of the twenty year period of patent protection within which to enjoy exclusivity from competition.

1 Source: CCSS, *op.cit.*, pp. 17, 18.

SAMENVATTING

Het kost de gewone burger niet lang om één of twee gevolgen van handelsovereenkomsten voor het leven in een mondiale wereld te bedenken. Publieke debatten over de impact van de bescherming van intellectuele eigendomsrechten op de toegang tot medicijnen of op de bescherming van het culturele erfgoed van inheemse volkeren leidden eerder dit decennium tot bezorgdheden, als ook de benarde positie van West-Afrikaanse katoenboeren en Caribische bananenproducenten die niet in staat waren te concurreren met de Amerikaanse en EU-subsidies. Protesten gedurende de handelsonderhandelingen in Seattle en elders leidden tot ongerustheid over de mate van democratie in handelsfora. Zorgen over negatieve gevolgen van handelsovereenkomsten lokten tegenargumenten uit. Handelsakkoorden zouden persoonlijke vrijheid mogelijk maken, menselijke welvaart vergroten, maatschappijen opener maken, democratieën en de rechtstaat versterken en economische groei en werkgelegenheid bevorderen. Deze debatten hebben een reeks van vraagstukken te sprake gebracht, waarvan er velen gerelateerd zijn aan mensenrechten, zoals het recht op gezondheid, het recht op voedsel en rechten ten aanzien van participatie in democratie.

Een robuust debat heeft geleid tot de oproep dat handelsbeleid gevormd moet worden op basis van bewijs dat de sociale gevolgen van handelsovereenkomsten in overweging neemt. Dit heeft bijgedragen aan de ontwikkeling van effectanalytische methodologieën, waarmee ontwikkelings-, milieu en sociale gevolgen van handelsbeleid geanalyseerd kunnen worden. Daarnaast is uit het eerdergenoemde debat een oproep voortgekomen tot het verrichten van mensenrechtelijke effectanalyses (HRIA) van handelsovereenkomsten. Dit proefschrift streeft ernaar de discussie over HRIAs van handelsovereenkomsten te verdiepen en de voordelen en risico's ervan te beschouwen om zodoende te bepalen of HRIAs meer systematisch ondernomen zouden moeten worden.

De centrale vraag van dit proefschrift is als volgt:

Is het op systematische manier ondernemen van HRIAs van handelsovereenkomsten waardevol?

Om een antwoord op deze vraag te geven, is het noodzakelijk eerst twee deelvragen te beantwoorden:

1. Welke voordelen bieden HRIAs voor de beoordeling van handelsovereenkomsten?
2. Wat zijn de risico's die verbonden zijn aan het ondernemen van HRIAs?

Dit proefschrift ontwikkelt een mensenrechtelijk raamwerk, demonstreert zijn originaliteit en identificeert een stapsgewijze methodologie voor een HRIA. Het illustreert de methodologie door middel van een studie van de impact van de Centraal-Amerikaanse Vrijhandelsovereenkomst (CAFTA) op mensenrechten. Deze studie legt vooral de nadruk op de intellectuele eigendomsregels van CAFTA, welke regels verdergaander zijn dan de WTO vereisten, en de gevolgen die deze regels zouden kunnen hebben voor de potentiële toegang tot essentiële medicijnen en mensenrechten. De studie concludeert dat de intellectuele eigendomsbepalingen in CAFTA waarschijnlijk druk zullen zetten op de capaciteit van de Costa Ricaanse regering in het verzekeren van universele toegang. Daarentegen bieden de solide institutionele structuren en de mensenrechtenbescherming ten aanzien van universele toegang tot medicijnen de Costa Ricaanse burgers een goed middel om hun rechten te beschermen en gegarandeerde universele toegang tot essentiële medicijnen in stand te houden.

Op grond van deze methodologie en de case study van Costa Rica identificeert dit proefschrift verscheidene voordelen en risico's die met HRIAs geassocieerd worden. In termen van voordelen bieden de normen en de mensenrechtenstandaarden een raamwerk dat een bredere en diepgaandere analyse van de impact van handelsovereenkomsten mogelijk maakt. Het helpt de individuen die anders wellicht vergeten zouden worden tijdens de vorming van handelsbeleid, zich te versterken. Tegelijkertijd houdt het staten en handelsbedrijvende ondernemingen verantwoordelijk, evenredig aan de mate waarin zij mensen treffen. Onder de juiste omstandigheden verbinden HRIAs de analyses van handelsakkoorden aan gerechtigheidmechanismen en internationale netwerken van mensenrechtenorganisaties die gewicht en urgentie aan de resultaten van de beoordelingen kunnen toevoegen. Terwijl het mensenrechtelijke raamwerk niet noodzakelijkerwijs de antwoorden hoeft te bieden op basis waarvan handelsbeleid aangenomen zou moeten worden, bieden HRIAs wel een manier voor het in twijfel trekken van handelsregimes, het verschaffen van bewijs ten aanzien van hun gevolgen en het stimuleren van nieuwe manieren van denken ten aanzien van handelshervorming. Het mensenrechtelijke raamwerk dat ten grondslag ligt aan HRIAs biedt een nieuw perspectief op concepten die zowel in mensenrechten als handelsrecht voorkomen, zoals 'vrije' handel en 'non-discriminatie'.

In termen van risico's onthult de analyse vervolgens dat de kracht van het mensrechtelijke raamwerk ook zijn zwakte kan zijn. Mensenrechtelijk vocabulaire kan contraproductief zijn en daarbij een aantal belangrijke actoren afschrikken en irriteren. Terwijl het voor individuen verenigend en versterkend kan werken, kan het juist versplinterend en bedreigend zijn voor regeringen en anderen. Hoewel potentieel invloedrijk, kan de analyse leiden tot een over-politisering van mensenrechten en het op een afstand houden van belangrijke spelers, met name gouvernementele actoren. In landen waar een mensenrechtelijke cultuur niet bestaat, kan het element van politisering de voordelen van het mensenrechtelijke raamwerk ondermijnen. Zelfs in landen waarin een mensenrechtelijke cultuur wel bestaat, zouden overheden terughoudend kunnen zijn in het uitvoeren van HRIAs in plaats van sociale effectanalyses,

omdat de HRIAs handelingen en beslissingen van de overheid in verdergaande mate kunnen blootstellen aan juridische beoordelingen.

Daarnaast kan het mensenrechtelijk discours gemanipuleerd worden of gebruikt worden voor doeleinden die niet noodzakelijkerwijs de doelstellingen van de methodologie, zoals ontwikkeld in dit proefschrift, zouden ondersteunen. Dit kan zich voordoen wanneer mensenrechtelijk discours gebruikt wordt om huidig handelsbeleid te verdedigen als zijnde van een constitutionele of fundamentele waarde. Op deze manier zouden mensenrechten wellicht gebruikt worden als instrument om de *status quo* te handhaven in plaats van ter bekritisering van het beleid. Ook inadequate, onderontwikkelde of ontoegankelijke juridische raamwerken en juridische normen die niet voldoende gedefinieerd zijn om een meetbare standaard te bieden, kunnen de voordelen van het juridische raamwerk van mensenrechten verminderen. Bovendien maakt de veelomvattende aard van het mensenrechtelijke raamwerk het vanuit de optiek van vaardigheden als ook van benodigde tijd en middelen bezwarend om HRIAs effectief te ondernemen. Al deze factoren kunnen de voordelen van het mensenrechtelijke raamwerk van HRIAs matigen.

Dit leidt tot de centrale vraagstelling die ten grondslag ligt aan dit proefschrift: *Is het op een systematische manier ondernemen van HRIAs van handelsakkoorden waardevol?* Er bestaat geen eenduidig antwoord op deze vraag. 'Waardevol' hangt af van de mate waarin de voordelen de risico's tenietdoen en er bestaat geen simpele rekensom voor deze vaststelling. Veel hangt af van het ontwikkelen van manieren om in de strategie de voordelen te maximaliseren en de risico's te minimaliseren. Veel van de risico's kunnen aangepakt worden door alle relevante actoren erbij te betrekken zodat zij een gevoel van 'ownership' krijgen met betrekking tot de analyse. Door het erbij betrekken van handelsinstituties kunnen de resultaten van de analyse wellicht invloed hebben in diezelfde instituties. Dit al verzekert een uitgebalanceerde analyse waarin zowel de positieve als negatieve gevolgen van het akkoord naar voren komen. Hiermee wordt een doorgrondige en betrouwbare analyse verzekerd die uitsluitend conclusies trekt op basis van solide bewijs.

Een belangrijke factor in het verzekeren dat de voordelen van HRIAs de risico's tenietdoen is het ondernemen van HRIAs in landen waarin een sterkere of opkomende cultuur van mensenrechten heerst. Met andere woorden, het is waarschijnlijker dat landen met expliciete juridische bescherming van mensenrechten en relatief sterke instituties en een actieve en open maatschappij, de juiste condities verschaffen voor de gunstige aspecten van het mensenrechtelijke raamwerk als een middel voor juridische analyse en hervormende verandering door middel van instituties. Deze factoren zouden allemaal ertoe bijdragen situaties te identificeren waar de voordelen van HRIAs naar voren komen en waar het waarschijnlijk 'waardevol' is om HRIAs op een systematische manier te ondernemen.

Bovendien is er een subjectief element verbonden aan 'waardevol' en hangt er veel af van welke actor of actoren van plan zijn HRIAs te ondernemen. Het is op zijn minst waarschijnlijk dat mensenrechtelijke actoren als Nationale Mensenrechten Instituties, mensenrechtenlijke NGOs, academische instituties en speciale procedures van de

Mensenrechten Raad het op een systematische manier ondernemen van HRIAs waardevol vinden. Andere actoren, inclusief bredere maatschappelijke organisaties, academici, handelsvakbonden, parlementariërs en zelfs enkele regeringen zouden ook 'waarde' kunnen zien in het op een systematische manier ondernemen van HRIAs. Daarentegen, zouden veel regeringen gevoelig kunnen zijn voor risico's van politisering en zouden zij de voorkeur kunnen geven aan het vermijden van het verantwoordingsraamwerk van HRIAs. Daarom zouden zij waarschijnlijk minder 'waarde' kunnen zien in HRIAs.

Desalniettemin, het op een systematische manier ondernemen van HRIAs lijkt toch 'waardevol' te zijn. Dit zou eerst een test moeten omvatten van de methodologie, gevolgd door een herbeoordeling van de vraag naar de 'waarde'. Het testen van de methodologie zou landen moeten identificeren die de verschillende voorwaarden vervullen en die demonstreren dat zij over een cultuur van mensenrechten beschikken of dat deze in opkomst is, hetgeen zou kunnen blijken uit solide instituties, een actieve maatschappij en normatieve helderheid en verantwoording. Waar sommige of al deze voorwaarden bestaan en strategieën om risico's te minimaliseren worden nagevolgd, bieden HRIAs een grotere mogelijkheid om de analyse van handelsovereenkomsten te verbreden en te verdiepen en bieden zij een stimulans voor de vorming van handelsbeleid op basis van bewijs en op manieren die voortbouwen op en verdergaand zijn dan andere effectanalyses. Zodoende zouden HRIAs in staat moeten zijn ons te helpen een 'vrije' handelsagenda voor te stellen die de doelstellingen van een non-discriminatoir en open handelsregime behoudt en deze combineert met doelstellingen voor het promoten van eerlijkheid en gelijkheid, daarbij vertrouwend op een verantwoordelijke en proactieve Staat, ondernemingsrechtelijke aansprakelijkheid en de versterking van de positie van kleine boeren, arbeiders, inheemse gemeenschappen, mensen die toegang hebben tot essentiële goederen en diensten en anderen voor wie handelsakkoorden kunnen en zouden moeten werken.

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Simon Walker was educated at the University of New South Wales, graduating with a Bachelor of Law and a Bachelor of Arts. He began his professional career as Associate to Justice Michael Kirby when he was President of the New South Wales Court of Appeal and Representative of the UN Secretary-General for human rights in Cambodia. After working two years as a Solicitor for Clayton Utz, he moved to Geneva where he did an internship for the Office of the UN High Commissioner for Human Rights (OHCHR). He worked for one year for the World Intellectual Property Organization examining how the use of intellectual property rights can affect the transfer of environmentally-sound technology. Subsequently, he returned to OHCHR where he has worked on a series of mandates including the right to development, human rights and trade, human rights and business, and legal protection of economic, social and cultural rights. In 2006, he became Advisor on Human Rights and Disability where he followed the adoption and entry-into-force of the Convention on the Rights of Persons with Disabilities for OHCHR. Simon Walker is currently the Human Rights Advisor to the UN Country Team in Albania. He has published widely on human rights issues, in particular on issues related to trade agreements.

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