

Moving Theory into Practice: Human Rights Impact Assessment of Intellectual Property Rights in Trade Agreements

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Abstract

This article explores the development of methodologies for human rights and right to health-specific impact assessment of trade-related intellectual property rights. These methodologies seek to respond to the restrictive impact of international and bilateral trade rules on domestic and global policy options to ensure access to affordable medicines in low and middle-income countries. Methodologies for right to health-specific impact assessment are emerging from human rights impact assessments, themselves an offshoot from the broader field of social and health impact assessment. A right to health-specific impact assessment allows policymakers to prospectively predict the impact of intellectual property rights on domestic medicines policy, and therefore on the realization of legal duties under the international human right to the highest attainable standard of health. The effective implementation of such an assessment provides an evidence base for broadening policy space in these countries towards improving access to generic and affordable patented medicines. Yet there has been little consensus to date on key questions of principle, methodology and implementation. We overview current literature and practice in this regard in order to assess the current state of the field and the prospects for wider-scale implementation. We first assess the growing international focus on the impact of trade-related intellectual property rights on access to medicines. We then explore the emergence of impact assessments in relation to health and human rights. Finally, we analyse the practical, methodological, political and theoretical challenges of right to health-specific impact assessment, and overview developments in practice and scholarship that suggest effective responses to these challenges.

Keywords: essential medicines; human rights impact assessment; intellectual property rights; international trade; right to health

Introduction

States are increasingly adopting legal and contractual obligations regarding trade, investment and aid that may negatively affect their abilities to comply

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with a variety of human rights obligations. These adverse impacts have led to a growing focus within the human rights community, including within this journal, on the contribution of impact assessments to protecting human rights against competing political, economic or commercial imperatives (Walker 2011; Harrison 2011; Bakker et al. 2009). Indeed, a growing consensus is converging in scholarship, global policy and various practice communities that human rights impact assessment may offer a pragmatic means of broadening policy space to protect against the potentially negative impacts of global trade and economic regimes on human rights.

The threats to human rights are particularly stark when it comes to the impact of trade-related intellectual property rights on access to affordable medicines in low and middle-income countries. An increasing number of states are bound by stringent international intellectual property rights through the World Trade Organization's (WTO's) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).¹ Moreover, bilateral and regional free trade agreements that require even stronger protection of intellectual property rights than TRIPS are proliferating. These so-called 'TRIPS-plus' intellectual property rights threaten to exacerbate existing gaps in access to essential and other medicines in low and middle-income countries. In this regard, TRIPS-plus intellectual property rights appear to conflict with the duties that governments hold to realize the right to the highest attainable standard of health ('right to health'), including the duty to ensure access to affordable medicines. Yet most policymakers currently do not consider right to health duties when negotiating or implementing stringent intellectual property rights in agreements relating to free trade and other commercial enterprises.

In this light, a growing number of health and human rights-oriented impact assessments are being conducted in relation to increasingly stringent intellectual property rights within free trade agreements, with varying impacts on health policy and health care access. The purpose of a human rights impact assessment is to predict the potential effect of a proposed policy on the enjoyment of human rights. The impact assessments diverge considerably, however, in the extent to which they incorporate human rights components and in the nature of the methodologies that they utilize. Moreover there has until recently been little in the way of pragmatic guidelines that could enable wider-scale implementation of these crucial instruments for realizing human rights. We step into these debates by overviewing and evaluating current literature and practice in order to clarify current consensus regarding human rights and right to health-specific impact assessment in relation to trade-related intellectual property rights and accessibility to medicines.

1 Agreement on Trade-Related Aspects of Intellectual Property Rights. 1994. Annexure 1C to the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco 15 April 1994.

The article proceeds in three sections: section 1 provides background on the limited access to medicines in low and middle-income countries, the impact of international law on trade-related intellectual property rights on access to affordable medicines, and the rising global recognition of the need to take account of the impact of these trade rules on the realization of human rights. Section 2 focuses on the emergence of human rights impact assessments from the broader field of health impact assessment, how these have converged in the development of right to health-specific impact assessments, and how practice and scholarship on human rights impact assessment of trade-related intellectual property rights has developed. In section 3, we analyse the practical, methodological, political and theoretical challenges of these approaches, and make recommendations for moving towards broader use of these tools as key components of realizing the human right to medicines.

1. The impact of trade-related intellectual property rights on the right to medicines

The need for human rights and right to health-oriented impact assessments of trade-related intellectual property rights is motivated by growing concern about the effect of these rules on access to affordable medicines globally, in both low and middle-income countries as well as high income countries. Despite international efforts to improve access to essential medicines, the chasm in access in low and middle-income countries—two billion people who lack regular access to essential medicines—continues largely unabated (World Health Organization (WHO) 2004; Millennium Development Goal (MDG) Gap Task Force 2013). While access to medicines is determined by several factors, such as rational use, adequate infrastructure, and sustainable financing (WHO 2004: 24), drug pricing can have a disproportionate impact on access. Recent studies confirm that in many low and middle-income countries, high medicines prices, and poor availability remain key impediments to access (Cameron et al. 2011: 2; MDG Gap Task Force 2013: 60). For example, a 2013 study found that from 2007 to 2012, the average availability of essential medicines in several low and middle-income countries was only 57 per cent in the public health sector and 65 per cent in the private sector (MDG Gap Task Force 2013: 60). Further, many essential medicines, especially for chronic diseases, continue to be prohibitively priced in low and middle-income countries, often 3.3 and 5.7 times higher in the public and private sectors respectively than international reference prices (ibid: 60).² Where medicines are not available free or at affordable prices in the public sector, people may be forced to choose between purchasing them in the private sector at prices they cannot afford and becoming impoverished, or going without treatment

2 International reference prices are the median prices offered to low and middle-income countries by non-profit suppliers, or the international tender prices set in the Management Sciences for Health International Drug Price Indicator Guide (MDG Gap Task Force 2012: 62–4).

for life-threatening and painful health conditions (Cameron et al. 2011: 6; Niens et al. 2010: 2). For example, a 2010 study exploring the affordability of medicines for asthma, diabetes, hypertension and adult respiratory infection in 16 low and middle-income countries found that large portions of the population (up to 86 per cent) would fall below the poverty line by purchasing these medicines; moreover, purchasing some original brand medicines, rather than the generic, would push more than three times as many people below the poverty line (Niens et al. 2010: 1).

International and bilateral trade agreements on intellectual property rights

Patents are the primary factor influencing the price of medicines. Since 1995, any country acceding to the WTO must protect patents under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which requires its members to provide 20-year exclusive protection to pharmaceutical patents. TRIPS introduced global minimum standards for the protection of patents, trademarks, copyrights and other intellectual property rights, and made extensive provision for their domestic and multilateral enforcement. This was the first time that international legal standards for intellectual property rights and patents had been harmonized in this way, inducing many countries (such as India) which previously had not patented medicines to do so, and requiring others to increase existing levels of patent protection (Bartelt 2003: 285).

While the primary purpose of TRIPS is to protect and enforce intellectual property rights, the agreement also seeks to ensure that intellectual property protection is neither abused by rights-holders nor abusive of public policy goals such as public health. As such, WTO members are authorized under TRIPS to adopt measures necessary to protect public health, promote the public interest and prevent the abuse of intellectual property rights. These measures include limited exceptions that enable states to either make or import cheaper drugs, such as parallel imports (whereby countries import cheaper patented medicines) and compulsory licensing (whereby countries manufacture or import generics under strict conditions) (TRIPS articles 6 and 31). Other provisions include the ability to set patentability criteria in relation to novelty and inventiveness, and to exclude from patentability inventions necessary to protect human, animal or plant life or protect health, as well as diagnostic, therapeutic and surgical methods for the treatment of humans or animals (TRIPS articles 27.1, 27.2 and 27.3(a)).

These exceptions are called TRIPS 'flexibilities' because they provide policy space to enable broader access to affordable medicines under monopoly pricing. Yet there is little that is flexible about these provisions and the environment in which countries seek to implement them, because countries that issue compulsory licences are likely to attract real or threatened trade sanctions as well as corporate litigation or removal of drugs from the domestic market in question.

These pressures motivated developing countries to push for a Ministerial Declaration at the Doha round of WTO trade negotiations in 2001 to clarify the legality of TRIPS flexibilities. The consequent Doha Declaration on TRIPS and Public Health confirms that

the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. . . . We affirm that the Agreement can and should be interpreted and implemented in a manner supportive of a WTO member's right to protect public health and, in particular, to promote access to medicines for all. (WTO Ministerial Conference 2001: 4)

The Doha Declaration also called for an expeditious solution to the problem created by the TRIPS requirement that compulsory licensing shall be 'predominantly for the supply of the domestic market', which particularly affected least developed countries without local manufacturing capacity. In August 2003, the WTO General Council released its decision to permit, under strict conditions, countries to import generic medicines produced under compulsory licences (WTO General Council 2003). This decision was made permanent in December 2005. Nonetheless, this decision has been used only once, in 2007, when the Canadian government amended national patent laws in compliance with this decision and a Canadian generic manufacturer sought permission to enter an export agreement with Rwanda for an antiretroviral HIV/AIDS drug (Elliott 2012: 156–7). This limited uptake of the WTO decision has been attributed to the fact that it provides a complex, costly and cumbersome process of limited duration (Hestermeyer 2007), an impact compounded by persistent corporate and governmental threats of legal and economic sanctions. These practical and political obstacles are illustrated in Canada, where the generic manufacturer in question made only two shipments of drugs to Rwanda over a six-year period and declined to renew the licence (Apotex 2010), and where legislative efforts to streamline the licensing process were voted down twice in parliament, at least in part because of industry opposition (Galloway 2012; *Toronto Star* 2012).

While there have been growing instances of low and middle-income countries successfully using other TRIPS flexibilities, like compulsory licensing to increase access to primarily HIV/AIDS drugs at affordable prices (Beall and Kuhn 2012), their use remains relatively rare (MDG Gap Task Force 2012: 67; World Intellectual Property Organization (WIPO) 2010). Moreover, a recent study shows that, despite a spike in the use of compulsory licences in the two years immediately following the Doha Declaration, there was a substantial decline in their usage from 2006 to 2011 (Beall and Kuhn 2012). This limited and declining usage of TRIPS flexibilities is attributable at least in part to economic, legal and diplomatic pressure from industry and their host governments in direct opposition to efforts to use these provisions, creating a chilling environment for other countries seeking to do so. Multiple examples

illustrate this point. In 2002, the US government pressured South Korea to refuse a compulsory licence for Gleevec, a leukaemia drug that costs around 27,000 US dollars per annum per person (Benvenisti and Downs 2004). In 2006, when Thailand issued compulsory licences on antiretroviral medicines, the US Trade Representative placed Thailand on its 301 Priority Watch List citing 'a weakening of respect for patents', and Abbott Laboratories threatened to withdraw seven essential drugs from the country (Flynn 2007; Irvine 2007).³ In 2006, Pfizer sued a Philippine company and government officials in their private capacity to prevent parallel importing of a generic version of Norvasc, a hypertension drug (Sanjuan 2006).

The limited ability of countries to freely exercise the legal flexibilities spelled out in TRIPS is similarly underscored by seizures by European port authorities of 'counterfeit' Indian generic medicines bound for other countries, irrespective of the patent status of those drugs in either exporting or importing countries (Mara 2009). It is therefore unsurprising that only a limited number of countries have amended national laws to enable use of TRIPS flexibilities. A 2010 study, for example, found that only 50 per cent of 95 countries surveyed had adjusted national patent legislation to use the Bolar exception in TRIPS, which allows unauthorized use of a patented invention before patent expiry to obtain marketing approval of a generic product (WIPO 2010).⁴ Nor is it entirely surprising that in this environment some developing countries have legislated *against* the use of TRIPS flexibilities, as Sri Lanka did in 2003 after entering a free trade agreement with the USA which prohibited (rather than simply restricted) compulsory licensing and parallel importing (Labonté et al. 2010: 46).

While legislative prohibition of TRIPS flexibilities is relatively uncommon, the adoption of TRIPS-plus intellectual property rights, which restrict the use of TRIPS flexibilities, has become standard practice in free trade agreements that the USA and European Union (EU) enter into with low and middle-income countries. These 'TRIPS-plus rules', so called because they exceed the standards in the TRIPS agreement, extend monopoly pricing and limit market entry for generic medicines including through restricting the grounds on which compulsory licences can be issued; prohibiting parallel imports; restricting autonomy to decide patent criteria; limiting patent exclusions; limiting market approval for generic drugs; extending data exclusivity requirements and patent terms; and enabling 'ever-greening' provisions (the practice of taking out new patents on existing medicines in order to maintain monopolies) (Forman 2006: 190). This forms part of a larger expansion of these agreements. For example, as of July 2013, the WTO reported receiving some 575 notifications of regional trade

3 The 'Special 301' Priority Watch List is a mechanism used by the US Trade Representative to undertake annual monitoring and reviews of intellectual property law and practices in foreign countries, and to impose sanctions on countries that fail to revise their patent laws.

4 Bolar exceptions allow experiments to be carried out on patented medicines to enable generic manufacturers to demonstrate the bioequivalence of their medicines before the patent expires.

agreements, 379 of which are in force (WTO 2013). The USA and EU are global leaders in promoting regional and bilateral agreements. Around 60 countries are bound by bilateral or regional free trade agreements negotiated by the USA (Forman 2006), and in 2012, the EU and European Free Trade Association had signed or were negotiating free trade agreements with over 50 developing countries (European Commission 2012; European Free Trade Association 2012).

TRIPS-plus intellectual property rights have expanded well beyond free trade agreements in a range of other bilateral agreements. For example, the Trans-Pacific Partnership being negotiated between the USA, Canada and 10 Pacific Rim countries (including Australia, Chile, New Zealand, and Peru) is likely to include stringent TRIPS-plus intellectual property rights that would expand patent monopolies and restrict access to generic medicines. A proposed Anti-Counterfeiting Trade Agreement (ACTA), in an effort to create an institutional mechanism to challenge the movement of counterfeit or pirated goods, uses a definition of counterfeit medicines that does not adequately distinguish between counterfeit medicines and legitimate generics produced under compulsory licence or where no patent is in force. The ACTA was proposed by Japan and the USA in 2006, joined by Canada, the EU and Switzerland from 2006–2007, with Australia, Mexico, Morocco, New Zealand, the Republic of Korea and Singapore joining the official negotiations in June 2008. While the European Parliament rejected the ACTA treaty in July 2012, effectively killing the operation of the treaty in EU member states, the USA and Canada are proceeding with efforts to operationalize this treaty (Sutton 2014).

The advancement of restrictive intellectual property rights of this nature continues despite the explicit endorsement in the Doha Declaration of WTO members' right to promote access to medicines through the full use of TRIPS flexibilities such as compulsory licences. The outcome is that legally permissible uses of TRIPS flexibilities continue to be attacked as impermissible breaches of TRIPS, threats to the medical innovation system, and outright theft and piracy. The net impact is to maintain high drug prices, restrict access to generics and sustain and even exacerbate the drug gap at great human cost (Forman 2012).

Calls for assessments of the impact of trade agreements on the right to medicines

Trade-related intellectual property rights threaten the realization of a range of human rights, particularly the right to the highest attainable standard of health. The international right to health was first proclaimed in the Constitution of the World Health Organization in 1946.⁵ Soon after, in 1948,

5 Constitution of the World Health Organization, adopted by the International Health Conference, New York, 19 June–22 July 1946; signed by 61 states 22 July 1946 (entered into force 7 April 1948).

the Universal Declaration of Human Rights (UDHR) recognized everyone's right to a standard of living adequate for health and well-being including food, clothing, housing and medical care and necessary social services (article 25).⁶ In the International Covenant on Economic, Social and Cultural Rights (ICESCR), adopted in 1966,⁷ state parties recognize everyone's right to the enjoyment of the highest attainable standard of physical and mental health, and agree to take steps to achieve this goal including preventing, treating and controlling disease and creating conditions to assure to all medical services and attention in sickness (article 12). Numerous other international and regional instruments protect the right to health (and therefore medicines), including the International Convention on the Elimination of Racial Discrimination (article 5(e)(iv)); the Convention on the Elimination of Discrimination against Women (articles 11(1)(f) and 12), the Convention on the Rights of the Child (article 24(1)), and most recently the Convention on the Rights of Persons with Disabilities (articles 9 and 25).⁸

International law is increasingly specific about the components of the right to health, including the entitlement to medicines. In 2000, in a seminal general comment on the right to health, the UN Committee on Economic, Social and Cultural Rights (CESCR), responsible for monitoring implementation of the ICESCR, indicated that this right places duties on governments to ensure both adequate levels of health care as well as underlying determinants of health (including water, sanitation, food, nutrition, housing, and healthy occupational and environmental conditions) (UN CESCR 2000: para. 11). The comment further provides that states hold a general duty to ensure access to affordable, available and safe drugs, and a minimum core duty to provide universal access to essential medicines (ibid: paras 12(a), 12(b), 43(d)).

In a 2006 general comment, the Committee explicitly addressed the clash between the right to health and intellectual property rights. The Committee urged state parties to ensure that their protection of intellectual property rights not impede their ability to comply with their duties under the rights to food, health and education, and that this means that state parties 'have a duty to prevent unreasonably high costs for access to essential medicines ... from undermining the rights of large segments of the population to health' (UN CESCR 2006b: para. 35). The Committee indicated that human rights are

6 Universal Declaration of Human Rights, adopted by UN General Assembly resolution 217A(III), 10 December 1948.

7 International Covenant on Economic, Social and Cultural Rights, 16 December 1966 (entered into force 3 January 1976).

8 International Convention on the Elimination of All Forms of Racial Discrimination, 7 March 1966 (entered into force 4 January 1969); Convention on the Elimination of All Forms of Discrimination against Women, 18 December 1979 (entered into force 3 September 1981); Convention on the Rights of the Child, 20 November 1989 (entered into force 2 September 1990); Convention on the Rights of Persons with Disabilities, 13 December 2006 (entered into force 3 May 2008).

fundamental, inherent to being human and timeless, whereas intellectual property rights are state tools intended to provide incentives for inventions, are generally of a temporary nature and can be revoked, licensed or assigned to someone else (ibid: paras 1–2). Accordingly, states should proportionally limit intellectual property rights to ensure a balance with public needs. While this comment specifically addressed essential medicines, in 2013, the UN Human Rights Council recognized that the human rights imperative to provide access to medicines encompasses ‘non-essential’ medicines as ‘fundamental elements’ of progressively realizing the right to health (UN Human Rights Council 2013: para. 2).

Given this recognition that access to medicines is a key element of the right to health, the past decade has seen a proliferation of calls from UN human rights institutions cautioning states negotiating or implementing trade-related intellectual property rights to assess their impact on people’s entitlement to accessible, available and good quality medicines. In 2001, the Office of the UN High Commissioner for Human Rights (OHCHR) recognized the potentially adverse impact of TRIPS on access to medicines and encouraged states to monitor implementation to ensure an appropriate balance between public interests and those of intellectual property rights holders (UN Commission on Human Rights 2001: para. 61). The OHCHR later made more explicit calls for human rights impact assessment of trade agreements by states, the private sector and international institutions, suggesting that these should take place both during policy and project formulation and after implementation, be public and participatory, focus in particular on disadvantaged and vulnerable groups and highlight the differing impacts of projects and policies on men and women (UN Commission on Human Rights 2005: para. 50).

In 2004, 2006 and 2008, the CESCR’s concluding observations for Ecuador, Morocco and Costa Rica strongly urged policymakers in each country to conduct assessments of the effect of international trade rules and free trade agreements on the right to health for all, to ensure access to generic medicines (UN CESCR 2004: para. 55; 2006a: para. 56; 2008: para. 48). In 2004 the UN Committee on the Rights of the Child (CRC) recommended that El Salvador conduct an assessment of the impact of international intellectual property rights agreements on the accessibility of affordable generic medicines, with a view to ensuring children’s enjoyment of the highest attainable standard of health (UN CRC 2004: paras 47 and 48). The UN Committee on the Elimination of Discrimination against Women (CEDAW) made similar calls in 2006 and 2007 for the Philippines, Guatemala and Colombia to study the impact of free trade agreements on the socio-economic conditions of women, and to consider compensatory measures that take women’s human rights into account (UN CEDAW 2006a: para. 32; 2006b: para. 26; and 2007: para. 29).

Calls for impact assessments of trade and trade-related intellectual property rights also come from UN entities beyond the human rights institutions. The 2008 report by the WHO’s Commission on the Social Determinants of Health

(CSDH Report) recognized that many low and middle-income countries have been discouraged from using TRIPS flexibilities (WHO 2008: 136–7), and urged countries considering new global, regional, and bilateral trade and investment commitments to establish flexibilities that would allow modifications in the event of adverse impacts on health or health equity (ibid: 14–15). The Commission is emphatic throughout its report that health equity impact assessment offers a key practical strategy for achieving these outcomes (ibid: 46, 135–7, Recommendations 12.1, 10.3, 16.7). Similar calls have been made in relation to the limited progress made under Millennium Development Goal (MDG) 8 on global partnerships for development, which aims in part to increase access to affordable essential medicines. In 2012 the UN MDG Gap Task Force (appointed by the UN Secretary-General in May 2007 to improve monitoring of MDG 8) argued that ‘developing countries should carefully assess possible adverse impacts on access to medicines when adopting TRIPs-plus provisions as part of bilateral or regional trade agreements’ (MDG Gap Task Force 2012: 72). A global consensus is therefore emerging that states should assess the impact of intellectual property rights in trade agreements on access to medicines, and do so from a human rights perspective.

2. The emergence of health and human rights impact assessments

These global calls draw in significant part from the emergence of impact assessments over the last 40 years as a major policymaking approach in a variety of areas (Walker 2009: 3; Harrison 2011: 3). Early impact assessments focused on the environmental impacts of construction projects in low and middle-income countries (Kemmm 2003), broadening out through the 1970s and 1980s to social impact assessment, which by the 1990s had become fairly common in policy processes (Walker 2009: 4). Around that time, a literature articulating a rationale and methodology for health impact assessment (HIA) emerged, (Krieger et al. 2003: 659), focusing increasingly on the impacts of public policy upon health and inequality (WHO 2002: 19). The primary objective of health impact assessment is to improve knowledge about the potential impact of a policy or programme to facilitate adjustments that will mitigate negative and maximize positive impacts (Gothenburg Consensus Paper 1999: 1). Health impact assessment does this by predicting the health consequences of decisions and thereby informing decision making (Kemmm 2003). Accordingly, health impact assessments have become viewed as important tools to improve health-related decision making and encourage public participation in policy debates (Scott-Samuel and O’Keefe 2007).

The aspirations for health impact assessment also move considerably beyond improving the health consequences of policymaking, including enhancing recognition of the social determinants of health; promoting inter-sectoral responsibility for health; engaging health professionals, policymakers and affected communities in discussions about the public health implications of public and private sector activity; and increasing awareness of the need for

transparent and accountable policy making (Krieger et al. 2003: 659–60). Indeed the hope is that health impact assessment will facilitate structural reform, at both the domestic and the global level, by ‘identifying health-damaging concentrations of power and locations from which alternative power structures may have a feasible chance of emerging’ (Scott-Samuel and O’Keefe 2007: 214). These broader aspirations are reflected in the 2008 CSDH Report’s endorsement of health equity impact assessment as a key practical strategy to prevent market pressures from impeding action on health equity (WHO 2008: 46, 135–7, Recommendations 12.1, 10.3, 16.7). Indeed, many scholars view impact assessment as a practical tool to minimize the negative health impacts of foreign policy and trade agreements on health and human rights (Lee, Ingram et al. 2007; Scott-Samuel and O’Keefe 2007; Walker 2009; Harrison 2011).

Given the potential influence of health impact assessment on domestic and global governance, human rights researchers and advocates have increasingly focused on developing impact assessments to measure and mitigate the social, environmental and economic impacts of policies, as well as to facilitate the realization of a variety of human rights. The adoption of human rights impact assessment (HRIA) coincides with a broader tectonic shift within the human rights field beyond traditional human rights methods of naming, shaming and litigating towards proactive policy approaches such as impact assessment, indicators and benchmarks capable of measuring the progressive realization of human rights (Chapman 2009: 106; UN Economic and Social Council 2009; Bakker et al. 2009: 438; Landman 2006; Backman et al. 2008). While traditional health impact assessment looks at the potential health effects of policy, HRIA focuses on the human rights implications of policies, and explicitly relies on standards drawn from international human rights law to measure change and assess potential impacts. Thus, in contrast to health impact assessment, HRIAs ask questions about the status of relevant human rights protections in international and domestic laws and frame recommendations in relation to these entrenched rights.

The development of HRIA has been prompted by a range of political factors, including donor efforts to determine the human rights impacts of foreign policy and technical cooperation programmes; efforts to increase corporate accountability; growing attention to social, economic and cultural rights; and increasing interest in human rights-based approaches to development among European donor agencies and at the UN as it mainstreamed human rights throughout the UN system in the late 1990s (Harrison 2011: 165; Walker 2009: 5–6). As a result, among the first human rights impact assessment tools were those intended to respond to development programmes (Norwegian Agency for Development Cooperation (Norad) 2001), foreign direct investment (Rights and Democracy 2008), and women’s health rights (Humanist Committee on Human Rights 2006).

Health and human rights-specific impact assessments

The twin strands of impact assessment in relation to human rights and health have increasingly converged in the development of human rights-focused health impact assessment and health-focused HRIA. Rather than creating human rights-specific impact assessments, some public health scholars have proposed incorporating human rights within existing health impact assessment and using such tools to evaluate public policy in a variety of realms, including international relations and foreign policy (O’Keefe and Scott-Samuel 2002; Scott-Samuel and O’Keefe 2007). Similar methodologies have been proposed by human rights scholars and practitioners including the first UN Special Rapporteur on the right to health (MacNaughton and Hunt 2009; Wu 2010). A more dominant approach has been to develop HRIA focused on health. Gostin and Mann articulated the progenitor of this approach in a seminal 1994 article which proposed the development of a methodological tool for assessing and mitigating the human rights impact of potentially coercive public health policies on vulnerable populations (Gostin and Mann 1994). They proposed a tool focused on health policy (rather than policy in trade or financial realms) and on the right of vulnerable populations to non-discrimination (rather than other human rights). In this vein, in 2011 Hinman adapted a methodology developed in 2004 by Lor to assess the human rights impacts of public health programmes upon a broader range of civil and political rights as well as upon social, economic and cultural rights (Hinman 2011).

The junction of health and human rights within impact assessment has also seen the creation of human rights and right to health-specific methodologies by NGOs and social groups, including the Canadian NGO Rights and Democracy, the Dutch NGO Aim for Human Rights, and the transnational People’s Health Movement (Bakker et al. 2009; People’s Health Movement 2006). One of the first HRIA methodologies was developed in 2004 by Rights and Democracy to be used by NGOs primarily to assess foreign direct investment projects. Their methodology follows a rights-based approach of assuring transparency, accountability and non-discrimination, focuses on vulnerable groups and recognizes the indivisibility of human rights. It also adopted the step-wise methodology commonly used in impact assessments of scoping (preparing the assessment plan), collecting information, reporting on findings, and making recommendations, followed finally by monitoring and evaluating. The tool has been applied in multiple countries including Argentina, Peru, Tibet, the Democratic Republic of the Congo and the Philippines (Rights and Democracy 2007).

The Health Rights of Women Assessment Instrument (HeRWAI) is the most widely used of these tools. It was developed from 2002 to 2006 by a group of NGOs located in the Netherlands, Kenya, Malaysia, Nicaragua and Bangladesh, who felt that the international mechanisms for monitoring state

accountability for women's rights needed to be bolstered by national processes (Bakker et al. 2009: 442). These groups developed HeRWAI as an advocacy tool to assist organizations to link policies to human rights issues, gather data and assess human rights impacts of policies, and pressure government to address their concerns (ibid: 443). The HeRWAI methodology embeds human rights standards from the Convention on the Elimination of Discrimination against Women and the International Covenant on Economic, Social and Cultural Rights into a step-wise approach which identifies the policy, groups of women affected and rights involved; identifies relevant law and policy that elaborate government commitments; describes the resources available to government to implement the policy and the factors impacting on implementation capacity; describes effects of the policy on women's health rights; establishes which effects are in areas where governments hold legal duties for which they can be held accountable; and finally, develops recommendations and strategies to enhance women's health rights (Aim for Human Rights 2010). Groups in numerous countries have conducted studies using HeRWAI as the basis for their advocacy efforts (Human Rights Impact Resource Centre 2014). HeRWAI also served as the basis for other HRIA models, including Gillian MacNaughton and Paul Hunt's right to health impact assessment methodology and the People's Health Movement tool.

In 2006, Hunt (who was then the UN Special Rapporteur on the right to health) and MacNaughton developed a methodology for a right to health-specific impact assessment that operates *ex ante* to assess prospective human rights impacts of proposed policies, and which is intended to be integrated into other forms of impact assessment (Hunt and MacNaughton 2006: 4–5). Unlike the tools for NGOs to carry out HRIAs which were developed by Rights and Democracy and by Aim for Human Rights, Hunt and MacNaughton's methodology was created for governments to proactively assess compliance with their human rights obligations. Drawing from the step-wise methodology, Hunt and MacNaughton propose a six-step approach, including (1) a preliminary check to establish if human rights assessment is required; (2) preparation of an assessment plan and distribution of information to stakeholders; (3) collection of information on potential human rights impacts of the policy; (4) preparation of a draft report comparing the potential impacts with state obligations under international human rights law; (5) distribution of the draft to stakeholders inviting feedback; and (6) preparation of a final report (ibid: 36–45). Hunt and MacNaughton ground this traditional impact assessment approach within foundational human rights principles, proposing seven principles for human rights impact assessment, including (1) using an explicit human rights framework; (2) aiming for progressive realization of rights; (3) promoting equality and non-discrimination in the policy process; (4) ensuring meaningful participation of all stakeholders; (5) providing information and protecting the right to free expression; (6) establishing accountability mechanisms for the state; and (7) recognizing the interdependence of all human rights (ibid: 33–4).

As these examples indicate, emerging models of HRIA share common elements, despite continuing variations in methodology, nature (i.e. whether stand-alone or integrated into other impact assessments), and proposed outcomes.

Impact assessment practice in relation to trade and the right to health

Actors have adopted a variety of health impact assessment and HRIA methodologies for assessing the impact of trade-related intellectual property rights on access to medicines. Outside the human rights arena, the most extensively used impact assessment methodology on intellectual property rights is the intellectual property rights impact aggregate (IPRIA) developed by Joan Rovira, a Spanish economics professor. The intellectual property rights impact aggregate is a user-friendly computer assisted simulation model to assess the impact of changes to intellectual property rights on domestic access to medicines, which can be used both *ex ante* (prospectively) and *ex post* (retrospectively) (Rovira et al. 2009: 4–12). The model is populated with information drawn from primary data and empirical studies where available, or estimates from other countries, expert opinion or assumed values where such data is not available (ibid: 12). The model has been applied in countries including Colombia, Guatemala and Costa Rica, and used in training workshops and by researchers to collect information in a range of other countries including Bolivia, Malaysia, Vietnam, Thailand, South Korea, Uruguay, India, Jordan, Dominican Republic and Costa Rica (ibid: 4). The model does not have any human rights components, albeit it has significant potential for integration into HRIA or vice versa.

HRIAs of trade agreements at the behest of governments have been relatively rare, despite far more common usage of health or social impact assessments. For example, the European Union Commission on Trade regularly contracts for ‘trade sustainability impact assessments’ that investigate the potential economic, social and environmental impacts of trade agreements so as to provide policy recommendations that may assist in the negotiation process (European Commission 2009b: 11). These trade sustainability impact assessments regularly include assessments of the potential impact of intellectual property rights within bilateral and regional trade agreements upon access to medicines within contracting countries, and have been conducted on agreements being concluded with Korea, Libya, Central America, India, and Canada (European Commission 2008, 2009a, 2009b, 2009c, 2011). While there is no human rights component to the intellectual property rights assessments, their findings are largely consistent with those articulated from within the human rights community. For instance the trade sustainability impact assessment of the EU–India Free Trade Agreement acknowledged that changes in the intellectual property rights regime would impact health and poverty through access to medicines, and that ‘the poor are especially vulnerable to major health risks and the situation is more sensitive if they do not have access to essential medicine’ (European Commission 2009c: 266). It concluded that commitments on

intellectual property rights should ‘therefore be construed in a way which does not impair the capacity of both parties to promote access to medicines in line with the relevant flexibilities built into the TRIPS agreement’ (ibid: 261). The trade sustainability impact assessment combines quantitative and qualitative analysis (using causal chain analysis, expert opinions and civil society involvement), and a step-wise process that includes preliminary studies of baselines, indicator selection, evidence-gathering, desk research and stakeholder consultation, analysis and recommendations.

The only HRIA of trade-related intellectual property rights conducted at government behest took place in Thailand in 2006 when the Thailand National Human Rights Commission considered the human rights implications of a free trade agreement being negotiated with the USA on agriculture, the environment, intellectual property and services and investment. This was also the first time that a human rights-based impact assessment of trade-related intellectual property rights was carried out by a low or middle-income country. From a methodological perspective, the report offers little in the way of guidance for other HRIAs of trade-related intellectual property rights. The intellectual property rights section used Rovira’s economic modelling approach as well as existing data to ground its conclusions that the free trade agreement would raise drug costs beyond people’s purchasing power and beyond the government’s annual health budget. It therefore recommended that the government delay negotiations and remove from the agreement intellectual property protection relating to drugs and public health services ([Thailand National Human Rights Commission 2006: 22, 56](#)).

This methodology, while certainly rigorous and valid, omits several of the more traditional stages of impact assessment such as screening, scoping or consultation. It also fails to incorporate consistent references to the Thai government’s binding human rights commitments under national and international law, or to tie its conclusions about the potentially negative impact of the free trade agreement to the government’s obligations for respecting, protecting and fulfilling human rights ([Forman 2012](#); [Harrison and Goller 2008](#)). The absence of a human rights framework for the impact assessment methodology does not necessarily imply limited potential to impact on policy outcomes. Without consistent integration of human rights principles and standards, however, the question arises whether this exercise can be considered a human rights rather than health impact assessment? On the other hand, inconsistent use of the traditional steps of impact assessment may be entirely appropriate in disparate political, economic and epidemiological contexts. Certainly the Thai experience illustrates how an impact assessment can be conducted relatively inexpensively and quickly using secondary data. The Thailand National Human Rights Commission report was never taken up in policy, however, as the ensuing military coup in 2006 indefinitely suspended free trade agreement negotiations and the issuing of a final report. Nonetheless, the Thai experience underscores the important contribution of a strong human rights culture and institutions to the likelihood of

HRIA being conducted. Here, the success of the HRIA was due to the existence of the national human rights commission, a supportive legal framework of domestic law and ratified international treaties, and a strong and independent civil society who actively triggered the assessment through petitions to the Commission and who disseminated the report broadly upon conclusion (Forman 2012).

In contrast, assessments by NGOs and scholars have been more commonplace, with numerous assessments conducted of the impact of trade-related intellectual property rights within prospective bilateral and regional free trade agreements (FTAs) upon access to medicines in particular countries. These include impact assessments of the USA–Andean FTA in Ecuador and Peru (3D 2004; IFARMA 2009); the USA–Dominican Republic–Central American FTA (CAFTA) on Costa Rica and Guatemala (Walker 2009; Shaffer and Brenner 2009); the USA–Morocco FTA (3D 2006); the USA–Australia FTA (Faunce et al. 2005); and the USA–Thailand FTA (Kessomboon et al. 2010). There is no uniformity of methodology within these assessments, but rather considerable variation in scope and depth. Many of the assessments lack an explicit human rights framework and do not follow any formal impact assessment methodology, such as Oxfam’s assessment of the USA–Jordan FTA, Shaffer and Brenner’s assessment of the USA–CAFTA in Guatemala, Faunce et al.’s assessment of the USA–Australia FTA, and IFARMA’s assessment of the USA–Andean FTA in Peru (Oxfam International 2007; Shaffer and Brenner 2009; Faunce et al. 2005; IFARMA 2009). Others have used methodologies that do not refer to human rights at all, like Rovira’s intellectual property rights impact aggregate to assess the impact of prospective free trade agreements on access to medicines in Peru and Thailand (IFARMA 2009; Kessomboon et al. 2010).

A separate strain of scholarship and practice has displayed a growing focus on the use of human rights or right to health-specific impact assessments, albeit with varying levels of specification of either human rights or impact assessment methods. For example, 3D’s analyses of prospective US free trade agreements in Morocco and Ecuador are less in-depth impact assessments than outlines of key concerns about potential impacts that are intended to provoke policy responses including the performance of full HRIAs (3D 2004, 2006). Wu’s model for right to health-specific impact assessment of trade-related intellectual property rights does not use a traditional impact assessment methodology. Instead, it proposes a series of questions designed to balance economic interests with human rights. It requires policymakers to examine burdens placed on the right to health by the policy in question; to evaluate the effectiveness of the policy in achieving its purposes, and in particular whether it is the least restrictive alternative to achieve such purposes; and to assess whether the trade-offs between the right to health and the policy are balanced and justified (Wu 2010: 184). While he does not explicitly indicate so, the questions Wu relies on draw significantly from the UN Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights, which suggest that

legitimate restrictions of rights must be both necessary and proportional—in other words, ‘the least restrictive alternative must be adopted where several types of limitations are available’ (UN Commission on Human Rights 1984: para. 29). Wu’s approach certainly offers pragmatic guidance regarding how states should assess trade-offs between intellectual property rights and human rights. However, while Wu’s approach is grounded in human rights theory, the series of questions it poses do not necessarily provide pragmatic guidance to policymakers regarding implementation.

Walker has developed the most detailed methodology to date for HRIA of trade-related intellectual property rights (Walker 2009, 2011). He adapts human rights-based approaches to development to propose four basic elements of a human rights impact assessment. First, human rights should be the explicit subject of a human rights impact assessment, which should cite to international human rights law instruments and norms, identify the rights holders affected by the policy and state and non-state duty bearers, identify human rights indicators to measure impact, and articulate its conclusions in terms of impact on human rights (Walker 2009: 30–32). Second, the process of the impact assessment should respect human rights, including using participatory assessment methods that ensure rights holders are active participants in the assessment rather than passive objects of study (ibid: 35–6). Third, impact assessment should contribute to developing the capacities of states and other actors to fulfil their duties to protect and promote human rights, as well as of individuals and groups to claim their human rights (ibid: 10). Fourth, impact assessment should involve human rights mechanisms and actors, including UN and regional treaty bodies, national human rights institutions, human rights NGOs and academics (ibid: 10, 37).

Walker proposes an *ex ante* methodology using the common step-by-step approach, including preparation, screening, scoping, analysis, conclusions and recommendations, and evaluation and monitoring (Walker 2011: 191–2). The scoping stage identifies hypothetical positive and negative impacts of the prospective trade agreement on human rights, establishing a baseline of the current state of human rights enjoyment within a country, looking at ratification of human rights treaties, national laws and policies, spending on medicines, and the position of vulnerable groups. At the scoping stage, actors identify qualitative and quantitative indicators and the most appropriate data collection techniques, including economic modelling, surveys, legal analysis, causal chain analysis, participatory case studies and expert opinion (ibid: 198–9).

Walker makes a significant contribution to the development of rigorous HRIA methodology that is finely tuned to the particularities of the trade context. He recognizes the causal challenges posed by trade agreements, and argues for a staged causal chain analysis that establishes the impact of a prospective free trade agreement on extending market exclusivity, identifies the impact of market exclusivity on prices, and assesses the impact of pricing on human rights and government capacity to ensure them (Walker 2011: 202).

Walker also identifies factors beyond the prospective free trade agreement that could impact along the causal chain, including key decisions made by policy-makers, national institutions, pharmaceutical companies and social actors. These include decisions with regard to (1) the legal implementation frameworks and the extent to which they limit market exclusivity and respond to pharmaceutical companies that engage in anti-competitive practices; (2) the capacity of national actors, such as the Patent Office and Ministry of Health, to avoid undue delays in granting patents and thereby extend market exclusivity; (3) the extent to which patent-holder pharmaceutical companies defend market exclusivity and generic pharmaceutical companies challenge ‘bad’ patents; and (4) the extent to which social groups and individuals use litigation, lobbying and other pressure tactics (*ibid*). These external factors suggest the legal and institutional reforms outside of the HRIA environment that may facilitate more human rights compliant interactions between intellectual property rights and domestic institutions.

3. Identifying and moving beyond the challenges of human rights impact assessment of trade-related intellectual property rights

The relatively novel application of human rights frameworks to impact assessment methodologies has raised distinctive methodological, technical and political challenges. The methodological challenge of measuring human rights compliance within HRIA draws at least in part from the relative infancy of the development of human rights-specific measurement tools such as indicators ([Green 2001](#); [Landman 2004](#)). Within HRIA scholarship, this has translated into a significant focus on the nature of human rights indicators that should be used in HRIA, and whether these should be quantitative and/or qualitative ([Bakker et al. 2009](#): 439–52). The question of indicator type is somewhat resolved since most HRIA methodologies now use a combination of qualitative and quantitative indicators ([Harrison 2011](#): 14), and strong human rights and right to health-specific indicators have recently been developed which can be used to populate such HRIAs—such as a seminal 2011 study developing 72 right to health-specific indicators for health system strengthening ([Backman et al. 2008](#)). Yet while the indicator challenge may be somewhat resolved in this respect, the broader challenge remains of standardizing HRIA methodologies in relation to trade-related intellectual property rights such that human rights principles and standards are fully integrated into each step of the HRIA.

In this light, the expertise required for HRIAs may pose resource challenges because conducting these kinds of impact assessments requires a solid grounding in human rights law and trade and intellectual property rights law, as well as impact assessment methodology. Similarly, the length of time and financial resources it may take to conduct an HRIA may pose challenges for resource-constrained governments. For example, the HeRWAI assessment can take two to four months to complete, while Walker’s HRIA took six months (Aim for

Human Rights 2010; Walker 2011: 208–9). Technical and resource challenges are compounded by the need to incorporate the participation of affected communities. While Walker suggests that these challenges may be limited in *ex ante* assessments where impacts have not yet occurred (Walker 2011: 210), participation of potentially affected communities remains a key component of HRIA and essential to understanding how affected communities may be impacted.

Potentially the biggest challenges of HRIA are political in that these instruments hold the potential to permit ‘rights-washing’, whereby governments can engage in ‘bureaucratic tick-box exercises’ (Harrison 2011: 171) which adopt ineffective safeguards or compensation provisions and permit the passage of agreements that harm rather than improve human rights (Berne Declaration et al. 2010: 4; Bakker et al. 2009: 437). The political challenges may be compounded in environments where governments are wary of human rights language that holds them accountable (Walker 2011: 208). These political and technical challenges are particularly acute in the trade and intellectual property rights context, given significant power differentials, which may make it tremendously difficult for a policymaker in a low-income country to propose mitigation measures irrespective of the strength of evidence adduced by an HRIA (Forman 2012). In the trade context, there are also significant challenges in establishing causality between prospective trade agreements and human rights impacts such as restricted drug access (Walker 2009). These dilemmas outline key questions regarding the implementation of an HRIA, including the kinds of countries, actors, methods and approaches best suited to ensuring effective uptake and implementation (Forman 2012).

Emerging consensus on principles and methodologies for human rights impact assessment of trade agreements

The specific challenges invoked by HRIA of trade agreements prompted expert consultations in 2010 and 2011 that assessed practice and human rights theory in order to propose guiding principles and methodologies (Berne Declaration et al. 2010; UN Human Rights Council 2011). These consultations reviewed the expanding body of practice and scholarship on HRIA in order to provide pragmatic and normative guidance for broad implementation of HRIA of trade and investment agreements.

In the report on the 2010 consultation, experts articulated HRIA as an important tool to be used in conjunction with or in addition to existing human rights strategies like mobilization, campaigning, advocacy, and research and policy analysis, for achieving ‘human-rights-friendly’ trade and investment regimes (Berne Declaration et al. 2010: 4). HRIAs were viewed as offering distinctive advantages over other forms of impact assessment precisely because they invoke the normative framework of human rights rooted in binding state commitments. The experts suggested that, to be effective, HRIA should be flexible, robust and user-friendly, draw on an independent multi-disciplinary

team, use valid and reliable indicators to focus data collection and demonstrate impact, and focus on both the negotiation process and outcomes of trade agreements (ibid: 9–13). The seminar identified a number of institutions that are particularly well equipped to conduct or call for HRIA, including ‘national human rights commissions, parliaments, UN agencies, human rights mechanisms and civil society organizations’ (ibid: 15). It also identified the step-wise approach to HRIA as including team selection, screening the issues, scoping the extent and methods of assessment—including indicators, data sources and processes, conducting the analysis, drawing conclusions and recommendations, and monitoring and evaluating outcomes (ibid: 13–14). The experts recognized that most work on HRIA methodologies had been undertaken in relation to intellectual property rights, and identified three methodological steps for HRIAs in this field: (1) identify the issues or provisions of patents, data protection and trademarks impacting on the right to health and access to medicines; (2) conduct an economic modelling exercise, for example, on prices of medicines, before, and five and ten years after, the agreement comes into force, which disaggregates impact on essential and non-essential medicines; and (3) analyse the impact on human rights beyond factors considered in economic modelling, including medicines availability, levels of domestic production, decreased availability of generic medicines and reliance on exports (ibid: 19–20). Participants in the 2010 consultation also recognized that effective implementation of its recommendations required international benchmarks in key areas including in relation to independence, fairness and transparency in process (of both HRIA and trade negotiations), stakeholder participation, the use of quantitative and qualitative indicators, adequate financing, and implementation of HRIA recommendations (ibid: 3).

Following the 2010 consultation, Olivier de Schutter, the Special Rapporteur on the right to food, drafted guiding principles for HRIA of trade and investment agreements through consultation with the experts at the 2010 seminar, other human rights actors and institutions and through public consultation (UN Human Rights Council 2011). The guiding principles propose a number of guidelines for conducting HRIA of trade and investment agreements. First, most innovatively, they suggest that conducting HRIA is not simply good public policy, but is itself a human rights legal obligation ensuing from the customary law prohibition on entering into agreements that impose inconsistent obligations (ibid: 5). In consequence, the guiding principles recommend that all states ‘prepare human rights impact assessments prior to the conclusion of trade and investment agreements’ (ibid: 5).

Second, the guiding principles maintain that states must ensure that trade or investment agreements not impose obligations inconsistent with treaty duties to respect, protect and fulfil rights (UN Human Rights Council 2011: 6–8). Third, they state that HRIA should be prepared before the conclusion of agreements in time to influence negotiations and followed, if necessary, by *ex post* evaluation. Fourth, while HRIA methodologies will differ depending

on context, each should be guided by key human rights principles including independence from the Executive negotiating the agreement, use of a transparent and non-discriminatory methodology, inclusive participation of affected communities, appropriate expertise and funding to conduct the HRIA, and parliamentary debate over HRIA recommendations (ibid: 9–11). Fifth, while there may be methodological variations, HRIA should make explicit reference to the normative content of human rights, incorporate human rights indicators into the assessment, and ensure that decisions on trade-offs are consultative, non-discriminatory and non-retrogressive (ibid: 11). Sixth, the guiding principles state that trade-offs should themselves contribute to human rights, and should be managed through processes that are participatory, non-discriminatory, non-retrogressive and with gains or losses equitably distributed (ibid: 12–13). Finally, the guidelines set out six steps for HRIA, namely, screening, scoping, evidence gathering, analysis, conclusion and recommendations and identification of evaluation mechanisms (ibid: 14).

Recommendations going forward

Scholarship and practice on this topic have converged to the point where fairly clear guidance can be drawn regarding key elements of implementing HRIA of trade-related intellectual property rights. This section of this article synthesizes guidance for implementing HRIA of trade-related intellectual property rights that can be drawn from the scholarship and practice overviewed in the article.

First, while the precise methods used will vary from context to context, HRIA should be flexible, robust and user-friendly and draw on a multi-disciplinary team that is independent from the Executive negotiating the agreement. Additionally, HRIA should use a transparent and non-discriminatory methodology, ensure inclusive participation of affected communities, draw on appropriate expertise and funding to conduct the HRIA, and result in parliamentary debate over HRIA recommendations (Berne Declaration et al. 2010: 9–13; UN Human Rights Council 2011: 9–11). Implementation teams should be pragmatic in implementation, tailoring processes to the availability of data and resources. For example, given the limited timeframes and resources available to conduct the HRIA, the Thailand National Human Rights Commission made effective use of secondary data in their assessment of the potential impact of the prospective USA–Thailand Free Trade Agreement.

Second, there is considerable consensus that the six stage step-wise approach to HRIA should be used, including (1) screening or preliminary analysis of the extent of the HRIA necessary; (2) scoping, including team selection, development of the methodology, selection of an explicit human rights framework based upon applicable human rights obligations and identification of data sources and indicators; (3) data collection; (4) analysis, requiring the evidence gathered to be compared against the human rights obligations; (5) reporting the conclusions and recommendations of the analysis as the basis for weighing

the options, decision making and holding decision makers accountable; and (6) monitoring and evaluating outcomes as they are implemented (Berne Declaration et al. 2010: 13–14; Hunt and MacNaughton 2006: 36–45; UN Human Rights Council 2011: 14).

Third, HRIA should combine quantitative and qualitative analysis using economic modelling, causal chain analysis, expert opinions and civil society involvement (European Commission 2009c; Walker 2011: 202; Berne Declaration et al. 2010: 19–20). Where economic modelling such as intellectual property rights impact aggregates are incorporated into HRIA methods, they should model impacts on prices of medicines before, and five and ten years after, the agreement comes into force, as well as disaggregate the impacts on essential and non-essential medicines for various segments of the population (Berne Declaration et al. 2010: 19–20). Additionally, impacts beyond factors considered in economic modelling should be incorporated, including availability of medicines, levels of domestic production, decreased availability of generic medicines and reliance on exports (ibid).

Fourth, explicit human rights frameworks should be integrated into HRIA. Such explicit incorporation would cite international human rights law instruments and norms, identify the rights holders affected by the policy and state and non-state duty bearers, identify human rights indicators to measure impact, and articulate conclusions in terms of impact on human rights (Walker 2009: 30–2; UN Human Rights Council 2011: 11; Hunt and MacNaughton 2006: 33–4).

Fifth, broad participation in the HRIA is both a key human rights principle and a key means of assuring accountability. This requirement derives from the right to participate in the conduct of public affairs, protected in article 25 of the ICCPR (Hunt and MacNaughton 2006). Participation is also key to enabling the capacity of rights holders to claim their rights and to developing a constituency that will advocate for the best policy option as framed by the HRIA. Without the participation of stakeholders, the results of the HRIA may never be taken up by policymakers and the options for mitigation or compensation will not accurately portray the interests of those likely to be negatively impacted.

Sixth, HRIsAs should be used in conjunction with, or in addition to, existing human rights strategies like mobilization, campaigning, advocacy, and research and policy analysis, for achieving ‘human-rights-friendly’ trade and investment regimes (Berne Declaration et al. 2010: 4). In particular, they should involve human rights mechanisms and actors, domestically (national human rights institutions, human rights NGOs, academics) and internationally (UN and regional treaty bodies) (Walker 2009: 10, 37; Berne Declaration et al. 2010: 15).

Governments should be clear about the range of potential responses that they can adopt in relation to HRIA results, including termination or amendment of the agreement, insertion of safeguards into the agreement, compensation from

third parties, or mitigation measures (UN Human Rights Council 2011: 8). In assessing which options to adopt, they should be guided by the human rights principles of necessity and proportionality, so that trade-offs between intellectual property rights and human rights impose the least restrictive impacts on human rights (Wu 2010; UN Commission on Human Rights 1984). Moreover, trade-offs should be consultative, non-discriminatory and non-retrogressive (UN Human Rights Council 2011: 11).

Finally, if, as De Schutter suggests, conducting HRIA is a human rights duty (UN Human Rights Council 2011: 6–8), then HRIA should be institutionalized within domestic laws and within the international system. Indeed, institutionalization is seen as a critical element of ensuring broader adoption of impact assessment in general, whether achieved through legislation, regulation or policy guidelines (Lee, Robbel and Dora 2013: 11). Within the international system, states should be required to integrate reporting on HRIA of trade-related intellectual property rights into their reports to various international human rights treaty bodies, including those that have specifically called on states to conduct impact assessments. Moreover, similar reporting should be integrated into state reporting on the advancement of Millennium Development Goal 8, and the post-2015 Sustainable Development Goals.

Conclusion

A growing consensus recognizes the causal impact of TRIPS and TRIPS-plus rules in sustaining and increasing medicines prices, and in limiting policy options for governments to increase access to essential medicines. A substantial literature generated by UN entities, human rights scholars and activists, and public health experts and practitioners now advocates for HRIA to be conducted in international trade negotiations related to intellectual property rights regarding the potential impact on the availability of medicines in middle and low-income countries. States hold not simply a public health but also human rights imperative to take feasible and practical steps to protect state capacities to realize their duty to increase access to affordable essential medicines. HRIA offers a pragmatic tool capable of mitigating the price impacts of trade-related intellectual property rights on access to medicines, and enabling states to comply with their human rights duties. It is more than time to move human rights principles into practice in this crucial area of health and access to medicines.

We hope that this article contributes to greater clarity on the practical, methodological, legal and political constituents of such actions, and the additional actions necessary to move towards wide-scale use of key human rights tools. Yet we note that to date, there has been no major HRIA study carried out that would permit comparisons of HRIA methodology, results and influence across countries, for example in the context of negotiations of a regional trade agreement on intellectual property rights. Governments and funders have not

stepped up to make this possible. As a result, evidence that human rights and health impact assessments have had measurable impacts on the outcomes of trade negotiations remains limited, potentially weakening policy resolve to carry out such exercises. While it is encouraging to see NGOs engaged in carrying out HRIAs, governments retain the primary obligation for ensuring that they do not adopt inconsistent legal obligations and for the realization of human rights, including the right to health and its component right to medicines. As such, governments should carry out HRIAs in the context of negotiations on international trade agreements pertaining to intellectual property rights and the potential effects on access to affordable medicines, and international human rights mechanisms should hold them to account for failing to do so.

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