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Abstract
In 2013, more than half the world’s poor continue to lack access to essential medicines, despite a multitude of global health diplomacy efforts to increase access to affordable medicines in low and middle-income countries. This failure is exemplified in Millennium Development Goal (MDG) Target 8E which aims to increase access to affordable medicines, yet fails to address key causes of unaffordability, including trade-related intellectual property rights under World Trade Organization (WTO) and bilateral and regional free trade agreement rules. This commentary argues that addressing these price impacts is key to effectively advancing access to medicines and that such measures should be incorporated into goals to replace the MDGs after they expire in 2015. One way to do so is through the use of human rights impact assessment (HRIA) of trade-related intellectual property rights to mitigate the price impacts of these rights and realize state duties in order to provide access to affordable essential medicines. An HRIA requires policy makers to assess the impacts of trade-related intellectual property rights on medicine affordability and access, and to accordingly remedy any negative impacts on medicines access. Multiple global health and human rights actors and institutions endorse their use, and significant attention has been brought to developing effective, robust and user-friendly methodologies. Global policy makers formulating post-2015 access-to-medicine goals should ensure that HRias are adopted as a pragmatic and widely agreed upon means of protecting drugs from a key structural determinant of inaccessibility, and realizing universal access as a prioritized aspect of the right to health.

Introduction
In 2013, more than half the world’s poor continue to lack access to essential medicines (World Health Organization, 2004), despite a multitude of diplomacy efforts to increase access to affordable medicines in developing countries. While inadequate access to medicines is multi-causal, an overwhelming policy consensus has emerged regarding the price impacts of international trade rules such as

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the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the even stronger “TRIPS-plus” intellectual property rights proliferating in bilateral and regional free trade agreements (FTAs). Yet this legal and political context is entirely absent from Millennium Development Goal (MDG) Target 8E which aims to increase access to affordable essential medicines in cooperation with pharmaceutical companies, and which has been largely ineffective. As the MDGs move towards expiration in 2015, there is a considerable focus at the international level on formulating their replacement goals. At present, discussions are focused on adopting an overarching health goal of healthy life expectancy, with universal health coverage as a subsidiary target (Editorial, 2013; United Nations, 2013). If the goal of universal health coverage is to effectively advance access to affordable medicines as a fundamental component of essential health care services, I argue that it must address the price impacts of trade-related intellectual property rights. One pragmatic and highly endorsed means of doing so is via human rights impact assessment (HRIA) of trade-related intellectual property rights, whereby policy makers assess and remedy the potential or actual impacts of trade-related intellectual property rights on access to medicines. This tool is recognized as offering a pragmatic mechanism for advancing the efficacy of global health diplomacy efforts (Lee, Ingram, Lock, & McInnes, 2007; Scott-Samuel & O'Keefe, 2007), and advancing access to affordable medicines. Multiple global health and human rights actors and institutions endorse the use of HRIA in relation to trade-related intellectual property rights, and significant attention has been brought to developing user-friendly methodologies to conduct HRIA.

Accordingly, this commentary will outline why HRIA should be adopted within post-2015 goals for medicines in the following way: first, by overviewing the current MDG target on medicines; second, by outlining the impact of TRIPS and TRIPS-plus trade rules on the affordability of medicines; and third, by locating the current proposal within the emerging global consensus regarding the use of HRIA in relation to TRIPS-plus intellectual property rights.

The MDGs and Access to Medicines

In September 2000, 189 heads of state meeting at the United Nations (UN) headquarters in New York issued the Millennium Declaration where they committed to global action to advance peace, the environment, good governance and development (United Nations, 2000, para. 11, 19-20). These commitments precipitated the creation of the MDGs: eight human development goals to be met by 2015 in relation to poverty, hunger, water, education, gender equality, child and maternal mortality, infectious disease, the environment and development (United Nations, 2000). Medicines are addressed in MDG 8, which aims to develop a global partnership for development through increased aid, non-discriminatory trade, debt relief, and improved access to medicines and information and communication technologies. Target 8E aims to, “in cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries,” measured via a corresponding indicator of “the proportion of the population with access to affordable essential drugs on a sustainable basis” (United Nations Statistics Division, 2013).

MDG 8E is distinctive from other goals for its lack of time-bound or quantifiable components. For example, other MDGs aim to achieve measurable results by 2015, such as reducing the maternal mortality ratio by three quarters or achieving universal access to treatment for HIV/AIDS for all those who need it (United Nations Statistics Division, 2013). The formulation of MDG 8E without such measurable or time-bound outcomes gives little guidance on how to evaluate progress under this target.
Moreover, it is unclear what advancing access to affordable essential medicines “in cooperation with pharmaceutical companies” requires. On one level, this terminology may be understood to extend to cooperative ventures such as public-private partnerships (PPP) between governments and pharmaceutical companies, which may positively enable drug access. Yet on another level, the implication of the language of MDG 8E is that using a measure like compulsory licensing to produce or import generic versions of patented medicines without the authorization of corporate patent holders could be viewed as an “uncooperative” approach to advancing access to affordable medicines, despite the legality of such measures under TRIPS.

Little progress has been made in increasing access to affordable essential medicines. A 2012 study shows that in many low and middle-income countries, the average availability of essential medicines remains low in the public health sector; at around 50.1 percent, versus 67 percent in the private sector (MDG Gap Task Force, 2012, 61). Many essential medicines, especially for chronic diseases, continue to be prohibitively priced in low and middle-income countries: often 2.6 and five times higher in the public and private sectors respectively than international reference prices (MDG Gap Task Force, 2012, 62-64). The global drug gap—two billion people who lack regular access to essential medicines—continues largely unabated (World Health Organization, 2004; MDG Gap Task Force, 2012).

TRIPS and TRIPS-Plus Rules

While access to medicines is determined by several factors, such as rational use, adequate infrastructure, and sustainable financing (World Health Organization, 2004, 24), drug pricing can have a disproportionate impact on access (Scherer, 2000; Caves, Whinston, & Hurwitz, 1991). Patents are the primary determinants of drug prices, and are protected internationally under the WTO’s TRIPS agreement. The TRIPS agreement requires 20-year patents for pharmaceuticals which give exclusive rights to patent holders to prevent non-consensual use. These rights are subject to extensive domestic and international enforcement including at the WTO’s dispute settlement mechanism. The TRIPS agreement permits exceptions to patenting in the interests of public health and social welfare (including compulsory licensing and parallel importing). However, governments may face considerable obstacles to the use of these “TRIPS flexibilities” including corporate litigation, unilateral trade pressures, and “TRIPS-plus” intellectual property rules adopted in bilateral and regional FTAs. “TRIPS-plus” rules limit the use of TRIPS flexibilities and are recognized as significantly limiting the capacity of states to increase access to affordable medicines (Smith, Correa, & Oh., 2009; Grosse Ruse-Khan, 2010). In response, developing countries successfully pushed for a confirmation of the legality of TRIPS flexibilities in the 2001 Doha Declaration on the TRIPS Agreement and Public Health (World Trade Organization, 2001). Despite the confirmation in the Doha Declaration that countries are legally entitled to use TRIPS flexibilities, governments that do so remain subject to significant economic and legal pressure, and the use of TRIPS flexibilities remains rare (MDG Gap Task Force, 2012, 67).

A Growing Consensus on Human Rights Impact Assessment

Trade-related intellectual property rights threaten the realization of a range of human rights including the right to health. This right is protected extensively in international law, with its most authoritative articulation contained in the International Covenant on Economic, Social and Cultural Rights (ICESCR) (United Nations, 1976). The right to health has been interpreted to impose a state duty to provide universal access to essential medicines as a core and hence prioritized duty under this right
Growing concerns about the impact of trade rules on state duties to realize access to affordable essential medicines has seen a rising consensus that policymakers should take the right to health into account when entering trade agreements. For example, several UN treaty-monitoring committees have called on countries to conduct assessments of the effect of international trade rules on the right to health (UNESCO, 2000; 2004; 2006; 2008; UN Committee on the Rights of the Child, 2004; United Nations Committee on the Elimination of Discrimination Against Women, 2006a; 2006b; and 2007). A similar call has been made in relation to TRIPS-plus rules (albeit without a specifically human rights approach) by the United Nations MDG Gap Task Force, appointed by the UN Secretary-General in May 2007 to improve monitoring of MDG 8. In 2012 the MDG Gap Task Force suggested, “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).

These global calls draw in significant part from the emergence of impact assessments over the last 40 years as a major policy approach in relation to the social, environmental and health impacts of governmental and private projects, programs and policies (Walker, 2009; 3; Harrison, 2011; 3; Kemm, 2003, 387). The primary objective of impact assessment is to improve knowledge about the potential impact of a policy or program, and facilitate adjustment to mitigate the negative and maximize the positive impacts (Gothenburg Consensus Paper, 1999, 1). Impact assessments do this by enabling policymakers to predict the consequences of decisions and inform decision making accordingly (Kemm, 2003). At the same time, there has been a significant growth in methodologies and scholarship exploring human rights impact assessments related to health (Hunt & MacNaughton, 2006; Humanist Committee on Human Rights, 2006; NORAD, 2001) and the impact of TRIPS and FTAs on access to medicines (Wu, 2010; Walker, 2009; Shaffer & Brenner, 2009; IFARMA, 2009; Faunce et al., 2005; Kessomboon et al., 2010; Rovira, Abbas, & Cortas, 2009; Oxfam International, 2007). Indeed, scholars widely view impact assessment as offering a practical tool to minimize the negative health impacts of foreign policy and trade agreements on health and human rights (Lee et al., 2007; Scott-Samuel & O’Keefe, 2007; Walker, 2009; Harrison, 2011).

Walker has developed a detailed human rights methodology for trade-related intellectual property rights (Walker, 2009; 2011), and Rovira has developed a simulation model to assess the impact of intellectual property rights that is being widely used (Rovira et al., 2009). In addition, international expert consultations have produced principles to guide flexible, robust and user-friendly human rights impact assessments of trade and investment agreements (Berne Declaration, 2010; United Nations General Assembly, 2011). These consultations and prior experiences suggest that HRIA should engage an interdisciplinary research team that would follow a step-by-step methodology to impact assessment. These steps include: (1) screening a prospective trade agreement for potential impacts, (2) scoping for potential its impact against a baseline of the current enjoyment of access to medicines, (3) analysing impacts, (4) drawing up conclusions and recommendations, and (5) conducting ongoing evaluation and monitoring of impacts (Walker, 2009; Berne Declaration, 2010; United Nations General Assembly, 2011, 14).

The policy guidance issued by these consultations reinforces global consensus about the practical contribution of HRIA in the realm of trade. Yet they go further, and suggest that conducting HRIA is itself a human rights duty, and that “all states should prepare human rights impact assessment prior
to the conclusion of trade and investment agreements” (United Nations General Assembly, 2011, 5). The time is therefore ripe for the wide-scale adoption of HRIA in order to protect access to affordable essential medicines against a key determinant of inaccessibility.

Conclusion

The limited success of MDG Target 8E in increasing access to medicines should inform global health diplomacy efforts to formulate post-2015 goals for increasing access to affordable medicines. A growing consensus recognizes the causal impact of TRIPS and TRIPS-plus rules in sustaining and increasing medicine prices, and in limiting policy options for governments to increase access to essential medicines. The policy imperative is to take feasible and practical steps to protect state capacities to realize their duty to increase access to affordable essential medicines. Human rights impact assessment of trade-related intellectual property rights offers one pragmatic tool capable of mitigating the price impacts of trade-related intellectual property rights on access to medicines, and enabling states to realize their human rights duties. Accordingly, a post-2015 goal on medicines that prioritizes public health needs as much as corporate interests should require policy makers to conduct HRIA when negotiating or implementing trade-related intellectual property rights in order to mitigate any negative price impacts.

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