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Health

Global Health Governance and Multi-Level Policy Coherence: Can the G8 Provide a Cure?

Heidi Ullrich

Working Paper No. 35

July 2008

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Thank you for your interest,

John English

Author Biography

Dr. Heidi Ullrich is an independent trade policy consultant for such organizations as the International Centre for Trade and Sustainable Development (ICTSD), GOPA and Gesellschaft für Technische Zusammenarbeit (GTZ). She has worked previously as Program Offer in Trade in Services at ICTSD in Geneva, Switzerland, and Global Trade Coordinator at Consumers International in London, UK. She has been a lecturer at the London School of Economics, where she also received her PhD, and at the University of Southampton. Her publications include articles on the G7/8 and trade policy, on the G8's role in multilateral negotiations, and on the G8, WTO and Public Governance. She has also written on the role of civil society in global governance and the interaction between the levels of rule making in trade in services. She is a member of the G8 Research Group at the University of Toronto and serves as Editor of its *G8 Governance* Working Papers.

Abstract

This paper highlights the ailing state of global health governance as evidenced by the lack of progress on the Millennium Development Goals (MDGs), in particular the goals related to health. Policy coherence within the global health governance system is not evolving fast enough to ensure that trade and development issues related to public health, particularly concerning access to medicines, are effectively aligned at national, regional, and multilateral levels. The paper briefly reviews the WTO Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and the 2001 Declaration on the TRIPS Agreement and Public Health. A case study outlines the manner in which "TRIPS-plus" provisions in selected US free trade agreements (FTAs) have undermined multi-level policy coherence in trade, development, and public health. The discussion then identifies three unique governance mechanisms of the G8 that make the group a potentially powerful catalyst for innovation in global health governance, and assesses the opportunities that the 2008 G8 Hokkaido Summit may offer. The paper concludes by offering recommendations for enhancing multi-level policy coherence and for strengthening the system of global health governance.

1. Introduction

With bilateral and regional free trade agreements (FTAs) proliferating between developed countries, specifically members of the Group of Eight (G8), and developing countries, the relationship between trade, development, and public health has become increasingly complex. Policy coherence in the global health governance system is not evolving fast enough to ensure that trade and development issues related to public health, particularly concerning access to medicines, are effectively aligned at the national, regional, and multilateral levels. As noted by the Organisation for Economic Co-operation and Development (OECD):

> Within national governments, policy coherence issues arise between different types of public policies, between different levels of government, and between different stakeholders. And the challenge goes beyond individual national governments. The interplay of developmental with other policies also occurs at *regional* and international level. The understanding of policy coherence needs to evolve to keep pace with increasing institutional and economic complexities. (OECD, 2003: 3, emphasis added)

Evidence that current global health governance is not effectively addressing the development dimension of public health is reflected in the slow rate of progress towards achieving the United Nations (UN) Millennium Development Goals (MDGs). The MDGs, established in 2000, are international targets intended to be realized by 2015 (see Annex 1). At this midway point in the period, the goals, targets, and indicators set in the MDGs for addressing global health are showing distressing symptoms.

- Progress on Goal 4 of reducing child mortality is still lagging in developing regions, particularly sub-Saharan Africa, although some progress has occurred on a global basis.[1] The UN estimates that the 10.1 million children who do not survive to their fifth birthday die mainly of preventable causes (UN, 2007: 14).

- Goal 5 addresses improvements to maternal health; yet over half a million women die annually from complications during pregnancy or childbirth that could be treated or prevented by better access to health services and medicines (UN, 2007: 16).

- The achievement of Goal 6 of combating HIV/AIDS, malaria, and other infectious diseases continues to be difficult in part because of increasing rates of HIV infection and the struggle to provide treatment. At the end of 2006, only 28 percent of HIV/AIDS sufferers in developing regions received the antiretroviral medicine they required (UN, 2007: 19).

- The proportion of the population with access to affordable, essential drugs is an indicator of progress toward Goal 8 of developing a global partnership for development (UNDP, 2008). However, according to the World Health Organization (WHO), one-third of the world's population does not have regular access to essential drugs (GAO, 2007:9).

The availability of essential medicines is closely connected with intellectual property rights (IPRs), specifically patents on

[1] According to UN estimates, the under-five mortality rate for sub-Saharan Africa of 160 per 1,000 live births is lagging far behind South Asia (83), East Asia (29), and Latin America (27) (UN, 2008).

pharmaceutical products. While proponents argue that patents provide financial incentives for pharmaceutical companies to develop life-saving medicines, others point out that pharmaceutical price levels can be prohibitively high for most people in developing countries. Since the early 1980s, developed countries and their industry representatives have increasingly seen IPRs as a trade-related issue (ICTSD/UNCTAD, 2003: 45). The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) came into being in part because governments recognized that new rules and disciplines were needed concerning "the availability, scope and use of trade-related intellectual property rights" (WTO, 1994: 366), From 1995, the newly established World Trade Organization (WTO) began incorporating IPRs into the multilateral trading system.

In 2001 WTO members adopted the Doha Declaration on TRIPS and Public Health (see Annex II). Considered a watershed declaration in terms of balancing pharmaceutical companies' need for economic incentives with the need of developing countries for increased access to medicines, the declaration explicitly acknowledges the need for coherence in trade, development, and public health policies through affirming that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all" (WTO, 2001: paragraph 4). The declaration re-affirmed several flexibilities within the TRIPS Agreement, including those related to parallel importing and compulsory licenses, which members could use in implementing the agreement.

Despite the positive step represented by the Declaration on TRIPS and Public Health, provisions within bilateral and regional FTAs recently negotiated by the United States (US) with both developed and developing countries reduce the effec-

tiveness of the declaration's flexibilities. At the same time, the FTAs represent a "drastic setback" to the declaration since they add further obligations on partner states that may weaken their access to medicines (Correa, 2006: 400) – in effect, making them "TRIPS-plus" agreements. Rhetorically, however, at the global level, the US continues to publicly support the declaration and its flexibilities.

Other developments with a bearing on the issue have included a resolution adopted in 2007 by the World Health Assembly, the governing body of WHO, to provide technical and policy support on TRIPS-related public health issues to developing countries,[2] and the establishment in 2007 of a Committee on Development within the World Intellectual Property Organization[3]. These two decisions support the movement towards greater global policy coherence in this field. But with the recent proliferation of regionally-based FTAs, another level has been added to the traditional global health governance system of international organizations, states, and private and public non-state actors – that of the regional level. The global health system must now take into account the growing regional dimension of trade policy. There is a need for greater multi-level policy coherence among trade, development, and public health policies at the global, regional, and national levels, particularly regarding access to medicines, in order to strengthen the health governance system. An innovative approach to ensuring multi-level policy coherence is required.

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[2] Resolution WHA60.30 (see http://www.who.int/gb/ebwha/pdf_files/WHA60/A60_R30-en.pdf)

[3] The decision to establish a Committee on Development within WIPO was agreed at the Fourth Session of the Provisional Committee on Proposals Related to a WIPO Development Agenda held 11-15 June 2007. See: http://www.wipo.int/ip-development/en/agenda/pcda07_session4.html. For more information on WIPO's Development Agenda see http://www.wipo.int/ip-development/en/agenda/

This paper briefly reviews the establishment of the TRIPS Agreement, including its key provisions on patents, as well as the Declaration on the TRIPS Agreement and Public Health and its relevance for policy coherence in trade, development, and public health. The paper then presents a case study of the manner in which TRIPS-plus provisions in selected US bilateral and regional FTAs have served to undermine multi-level policy coherence. The case study describes recent institutional developments that may require increased political commitment if they are to improve the situation. The discussion then examines the G8's record as a catalyst in global health governance and assesses the opportunities that the 2008 Hokkaido Summit may offer to increase policy coherence in this area.

One of the objectives of the G8 – the group of 8 developed countries, Canada, France, Germany, Italy, Japan, Russia, the United Kingdom and the United States, with the participation of the European Commission – is to reconcile tensions between international and domestic policies, and among the politics of participating nations. A second objective is "mobilizing the political leadership of heads of state and government to resolve problems beyond the reach of national bureaucracies or international organizations" (Bayne, 2000: 3). A third objective is the setting of commitments, through which members of the G8 serve as a source of mutual accountability. The paper examines whether the unique governance mechanisms of the G8 can be a source of leadership in strengthening multi-level policy coherence and curing the problems in the global health governance system.

2. The TRIPS Agreement and the Declaration on the TRIPS Agreement and Public Health

The primary force behind efforts to formulate and enforce stronger rules on trade-related IPRs came from industries in the

United States. Beginning in the early 1980s, pharmaceutical and technology companies argued that international rules covering IPR protection were limiting potential market access for pharmaceutical products in foreign countries, and that this was an issue inherently related to trade and the responsibility of the US government to solve (ICTSD/UNCTAD, 2003: 45).

By the time of the launch in 1986 of the Uruguay Round of multilateral trade talks, under the General Agreement of Tariffs and Trade (GATT), developing countries had agreed to only a clarification of existing GATT provisions on IPRs. But due mainly to industry lobbying and developing country fears that developed countries could impose unilateral trade sanctions on countries with weak IPR systems, a comprehensive TRIPS Agreement was reached by the conclusion of the Uruguay Round in 1994. This agreement creates basic principles on trade-related IPRs and provides for high levels of protection and enforcement covering such categories as patents, copyrights, and trademarks.

On patents, the TRIPS Agreement establishes a protection period of twenty years from the date of filing. This protection covers both the final product as well as the process involved in its development and manufacture. In addition to conferring rights to the patent owner, the agreement also allows certain exceptions to these rights in order to guard against anti-competitive behaviour of the patent holders. These exceptions include the granting of compulsory licenses to other producers in cases of public non-commercial use, national emergency, or other circumstances of extreme urgency, and the parallel importing of patented products from a third country where they are available at lower prices. Despite these exceptions, there was some doubt among WTO members over their interpretation and the extent to which use of these flexibilities would be allowed (WTO,

2003: 42). Consequently, the developmental aspects of these exceptions remained uncertain.

However, the preamble to the TRIPS Agreement clearly notes the right of member governments to achieve their developmental objectives, "recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives" (WTO, 1994: 366). Developing countries were granted a transition period of five years (1995-2000) for the implementation of the agreement, while least developed countries (LDCs) were given an eleven-year transition period (1995-2006).

Due in part to concerted efforts by developing countries and non-governmental organizations (NGOs) to clarify the relationship between trade, development, and public health as established by the TRIPS Agreement, and supported by analyses carried out by WHO and others,[4] WTO members adopted the Doha Declaration on the TRIPS Agreement and Public Health at the fourth WTO Ministerial held in Doha, Qatar from 9-14 November 2001. Of particular significance, paragraph 4 of the declaration states:

> We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. (WTO, 2001)

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[4] For more information on WHO's work on IPRs, medicines, and TRIPS, see http://www.who.int/medicines/areas/policy/globtrade/en/index.html

In order to clarify the specific flexibilities within TRIPS, paragraph 5 reaffirmed member governments' rights regarding the issuance of compulsory licenses, the definition of what constitutes a national emergency or other extreme urgency, and the exhaustion of rights (WTO, 2001). Paragraph 6 recognized that some WTO members lack the capacity to manufacture pharmaceutical medicines such as to reduce their ability to effectively use the compulsory licenses. It called on the WTO Council for TRIPS to find a solution by late 2002. Although this deadline was missed, a General Council Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Heath, which provided additional flexibility with respect to compulsory licenses, was adopted in August 2003. In December 2005, WTO members agreed to formally incorporate these flexibilities into the TRIPS Agreement upon acceptance by two-thirds of the WTO membership.[5] Finally, paragraph 7 of the declaration granted the lowest-income countries (LDCs) additional transition time through 2016 for implementation of TRIPS obligations with respect to pharmaceutical patents (see Annex 2 for the complete text of the declaration).

Given its emphasis on ensuring policy coherence among trade, development, and public health, the declaration has been described as "an attempt to ensure, through the effective use of the permitted flexibilities, some balance in the implementation of the TRIPS Agreement and, in particular, that public health be given priority in case of conflict with intellectual property rules" (Correa, 2006: 400). However, the US incorporation of TRIPS-plus provisions in bilateral and regional FTAs described in the paper, indicates a lack of multi-level policy coherence.

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[5] As of mid-January 2008, only 30 out of the 151 WTO members had accepted the changes set out in the 2003 Decision. The deadline for reaching the required two-thirds has been extended through 31 December 2009.

3. The Undermining of Policy Coherence in Development, Trade, and Public Health by Free Trade Agreements: A Case Study of the United States

The United States sees itself as a leading supporter of increasing the ability of countries to provide essential medicines to their citizens. Among its laudable efforts is the President's Emergency Plan for AIDS Relief (PEPFAR), announced at the 2003 G8 Summit in Evian, France, which has provided US$15 billion over five years for HIV prevention and treatment activities, including antiretroviral medication, in over one hundred countries. At the same time, the US consistently states its support for both the TRIPS Agreement as well as the Doha Declaration on the TRIPS Agreement and Public Heath.[6] According to the US Trade Act of 2002 that outlines US negotiating objectives for bilateral, regional, and multilateral trade negotiations, the US seeks to achieve three main goals with regard to intellectual property rights:

1. to further promote adequate and effective protection of IP rights, including through ensuring that the provision of any multilateral or bilateral trade agreement governing IP rights that is entered into by the United States reflects a standard of protection similar to that found in United States law;

2. to secure, fair, equitable, and nondiscriminatory market access opportunities for United States persons that rely on IP protection; and

3. to respect the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the World Trade Organization (GAO, 2007: 27-28).

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[6] See the website of the USTR's Office of Intellectual Property and Innovation: http://www.ustr.gov/Trade_Sectors/Intellectual_Property/Section_Index.html

However, analysis of the IPR provisions in the eleven FTAs that the US Trade Representative (USTR) negotiated between 2002 and 2007 provides evidence that the spirit, and indeed the letter, of the declaration is being violated. As shown in Figure 1, some of the FTAs include provisions on compulsory licenses and parallel importing, while nearly all include additional TRIPS-plus provisions on data exclusivity, patent extension, and patent linkage.

Figure 1: Recent US FTA Pharmaceutical-related IP Provisions and Side Letters

FTA	FTA status	Compulsory licensing	Parallel importing	Data exclusivity	Patent extension	Patent linkage	Side letter on public health	Per capita income
Chile	Implementing Leg. signed 9-2003	A	A	B	B	B	X	$12,983
Singapore	Implementing Leg. signed 9-2003	B	B	B	B	B	A	$32,867
Australia	Implementing Leg. signed 8-2004	B	B	B	B	B	A	$32,938
Morocco	Implementing Leg. signed 8-2004	A	B	B	B	B	B	$4,956
CAFTA-DR	Implementing Leg. signed 8-2005	A	A	B	B	B	B	$5,895
Bahrain	Implementing Leg. signed 1-2006	A	A	B	B	B	B	$23,604
Oman	Implementing Leg. signed 9-2006	A	A	B	B	B	B	$18,841
Peru	Agreement signed 4-2006	A	A	B	B	B	X	$6,715
Colombia	Implementing Leg. signed 11-2006	A	A	B	B	B	X	$8,091
Panama	Implementing Leg. signed 6-2007	A	A	B	B	B	X	$8,389
Korea	Implementing Leg. signed 6-2007	A	A	B	B	B	X	$23,926

A indicates that the provision is NOT present in the FTA; X indicates that language on the Doha Declaration and Public Health was incorporated into the body of the agreement; B indicates that the provision is present in the FTA

Source: GAO 2007

With respect to compulsory licensing, both the TRIPS Agreement and the declaration allow for their use. Article 31 of the

TRIPS Agreement covering other use without authorization of the right holder is based on the premise that a government retains full freedom to determine when a compulsory license may be issued "where the law of a member allows for other use." Although it sets out various examples of when a compulsory license may be issued including in the case of public non-commercial use, national emergency, or other circumstances of extreme urgency, the text is clear that these examples are only to "be respected." The declaration reaffirms and clarifies this flexibility by noting, "each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted" (WTO, 2001: paragraph 5b). However, in the bilateral FTAs that the US negotiated with Australia and Singapore, the US places limits on the use of compulsory licenses. For example, in the chapter on Intellectual Property Rights of the US-Singapore FTA, Article 16.7(6) states in part:

> Neither Party shall permit the use of the subject matter of a patent without the authorization of the right holder except in the following circumstances: (a) to remedy a practice determined after judicial or administrative process to be anticompetitive under the competition laws of the Party, [and] (b) in the case of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency. (USTR, 2003b: 195)

Article 17.9(4) in the chapter on Intellectual Property Rights of the Australian-US FTA, states:

> Each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from a patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory, at least where the patentee has placed restrictions on importation by contract or other means. (USTR, 2004c: 15)

This language on compulsory licensing clearly goes beyond that stated in the TRIPS Agreement and the declaration. It is notable that these provisions were not included in FTAs signed with developing countries post-declaration.

Pharmaceutical companies frequently sell their patented medicines at different price points in various overseas markets. The concept of parallel importing of patented pharmaceuticals allows countries to import patented pharmaceutical products without the consent of the patent holder in order to benefit from lower prices on these products. The principle of exhaustion enables parallel importing since it states that at the time a patent holder sells their product, they have exhausted their rights over this product and thus cannot prohibit its resale. Article 6 of the TRIPS Agreement allows for parallel importing, subject to provisions related to national treatment and most-favoured nation (MFN) treatment[7], through stating that practices relating to this activity cannot be challenged in the WTO's dispute settlement system. The declaration reinforces the right of countries to engage in parallel importation by stating that each member is "free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions" (WTO, 2001: paragraph 5d). In the case of US bilateral FTAs with Morocco, Singapore, and Australia, provisions grant the patent owners exclusive rights beyond the point of initial sale, thus significantly limiting the possibility of parallel importing. This limitation is clearly evident in Article 4 of the IPR chapter of the USA-Morocco FTA, which states, "Each Party shall provide

[7] National treatment and most-favoured nation treatment are key principles of non-discrimination within the global trading system. National treatment grants an imported item the same treatment in the domestic market as a locally produced item. Under most-favoured nation treatment, if a country grants another country a specific special trade favour, they must also grant the same favour to all other countries.

that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory" (USTR, 2004a: ch15, p19). As in the case of compulsory licensing, these provisions contravene those established in the TRIPS Agreements.

Although the provisions on compulsory licensing and parallel importing that violate the letter of the TRIPS Agreement and the Declaration on Public Health are limited to a few of the eleven FTAs that the US negotiated between 2002 and 2007, the additional, TRIPS-plus provisions on data exclusivity, patent extension, and patent linkage that go against the spirit of these documents are present in all.

Pharmaceutical producers, including producers of generic medicines, are required to show data related to the safety or efficacy of the medicine prior to gaining marketing approval. Under Article 39.3 of the TRIPS Agreement, WTO members are required to protect undisclosed test data or other data against unfair commercial use. According to Correa (2006), this provision "when correctly interpreted, [denotes that] members are not obliged to grant exclusive rights over data, as is done under the sui generis regimes established by the USA, the EU, and in other countries" (401). However, due to TRIPS-plus provisions on data exclusivity negotiated by the US in recent bilateral FTAs, generic pharmaceutical companies in the US and partner countries are not allowed to use the safety or efficacy information of the patent holder for at least five years. Therefore, unless the generic company produces its own test data, the patent holder will have five additional years of exclusive marketing rights (GAO, 2007: 29). This extension makes it much more difficult for less expensive generic medicines to enter a market.

The TRIPS Agreement grants patent holders a term of protection of twenty years (Art. 33). Patent term extension provisions in all of the US FTAs being analyzed grant the patent holder extensions of the patent terms for unreasonable delays related to the filing of the patent or gaining marketing approval. This provision grants additional rights to the patent holder over that of producers of generic medicines. Also, given that delays occur regularly in developing-country patent offices due to capacity constraints (Correa, 2006: 401), such provisions will further delay access to less expensive medicines for their citizens.

Similar to provisions on patent term extension, patent linkage provisions also provide greater rights to pharmaceutical patent holders than to generic producers through establishing a link between granting marketing approval for a generic drug and the term of protection on a patented pharmaceutical. Thus, health authorities are required to withhold granting marketing approval to generic producers of medicines "prior to the expiration of the patent term, unless by consent or acquiescence of the patent owner" (USTRa, 2003: 21). Additionally, the health authority is required to inform the patent holder of the name of the generic company requesting the marketing approval. Correa argues that this provision not only disregards the preamble of the TRIPS Agreement that recognizes IPRs as private rights, but also "shifts to the Members the responsibility of preventing possible infringement. Members also assume any liability for unduly preventing the approval of a generic product if it is finally determined that the patent is invalid or that there is no infringement" (Correa, 2006: 402).

In several of the FTAs being analyzed, various mechanisms that serve to somewhat soften the negative impact of TRIPS provisions related to public health are either included in the final texts or have been added in the form of a side letter or letter of

understanding. The texts of the FTAs with Colombia, Peru, Panama, and Korea include a paragraph stating "the Parties affirm their existing rights and obligations under the TRIPS Agreement and intellectual property agreements concluded or administered under the auspices of the World Intellectual Property Organization (WIPO) to which they are party" (USTR, 2006: Art. 6). The Chile FTA includes similar language in its preamble. In the case of the FTAs with Bahrain, Morocco, and Oman, as well as the Understanding Regarding Certain Public Health Measures with the Central American-Dominican Republic FTA (CAFTA), similarly worded documents have been signed, stating that with respect to the obligations within the IP chapters, "the Agreement [does] not affect the ability of either Party to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria and other epidemics as well as circumstances of extreme urgency or national emergency" (USTR, 2004b).

However, these mechanisms only serve to clarify certain IPR provisions within the TRIPS Agreement and the declaration and do not address TRIPS-plus provisions. Additionally, according to a 2005 US House of Representatives report:

> …the letters have only interpretive value. In the event that a brand name drug company challenges a decision to approve a generic drug produced under a compulsory license, the Bush Administration has acknowledged that the conflict will only be "informed" by the letter and will have to be "resolved on the merits of a particular case."[8] (US House of Representatives, 2005: 11)

[8] As noted in a letter from USTR General Counsel John K. Veroneau to Representative Sander M. Levin concerning the US-Morocco Free Trade Agreement (19 July 2004).

This same report concluded:

> Contrary to the principles of the Doha Declaration, the Administration has used these trade agreements to restrict the access of developing nations to low-cost generic drugs. By delaying generic drug approvals, extending patent terms, limiting compulsory licensing, prohibiting parallel importation, and otherwise restricting countries' efforts to improve access to affordable drugs, the trade agreements undermine the safeguards outlined in the Doha Declaration. These agreements may offer advantages to multinational pharmaceutical companies, but they do so at a serious cost to public health in the developing nations. (13)

Concerns raised by Members of Congress,[9] academics, NGOs, and producers of generic pharmaceuticals led to the Bipartisan Trade Deal in May 2007. This deal required the revision of some of the TRIPS-plus IPR provisions that had been subject to concern in the FTAs with Peru, Colombia, Panama, and Korea prior to being submitted to Congress for approval. The Bipartisan Trade Deal includes the following points:

- Clarification that the period of protection for test data for pharmaceuticals by developing country FTA partners will generally not extend beyond the period that such protection is available for the same product in the US, coupled with a provision that will encourage our partners to process marketing approval for applications for innovative drugs in a timely manner;

[9] The US Constitution grants Congress full authority in the area of international trade policy. However, since 1934 Congress has delegated its constitutionally mandated trade authority to the Executive on a limited but renewable basis, most recently through the granting of Trade Promotion Authority (TPA). Therefore, the Office of the United States Trade Representative has operational responsibility for negotiating US trade agreements at the bilateral, regional, and multilateral levels, but still is answerable to Congress.

- Clarification that developing country FTA partners may implement exceptions to normal rules for protecting test data to protect public health;
- A more flexible approach, for developing-country partners, to restoring patent terms to compensate for processing delays, accompanied by new provisions stipulating that trading partners will make best efforts to process patent and marketing approval applications expeditiously;
- More flexibility in terms of the types of procedures that developing-country partners may implement to prevent the marketing of patent-infringing products; and
- Integration in the intellectual property chapter of a recognition that nothing in the chapter affects the ability of our FTA partners to take necessary measures to protect public health by promoting access to medicines for all, and a statement affirming mutual commitment to the 2001 Doha Declaration on the TRIPS Agreement and Public Health. (GAO, 2007: 3)

Although the Bipartisan Trade Deal is a positive step in terms of complying with the letter of the TRIPS Agreement and the Declaration on Public Health, it falls short on at least two fronts. First and foremost, the deal addresses only the four most recently negotiated FTAs and not the many US bilateral or regional FTAs that have already been approved by Congress. Second, despite the greater flexibilities on IPR provisions mandated by the Bipartisan Trade Act, the USTR acknowledges that overall the intellectual property chapters of these four agreements are TRIPS-plus in nature, stating that they "continue to represent an enhancement of IPR protection for pharmaceutical products in those markets, compared to the status quo situation" and that "the results are fully in line with this Administration's long-standing trade policy objectives in the

area of intellectual property" (USTR, 2007: 3). Thus, US policy toward trade, development, and public health is not in the spirit of the Doha Declaration.

4. Can the G8 Provide a Cure?

Since 1996, the G8 has increasingly addressed the issue of global health and its governance. This attention has focused on such key health issues as access to medicines, HIV/AIDS, polio, funding of the Global Fund to battle HIV/AIDS, Tuberculosis and Malaria, and to a lesser extent development. At the 2003 G8 Summit in Evian, the G8 produced an Action Plan on Health that stated in part:

> …in partnership with others, including public-private partnerships, we will work to develop an integrated approach that will facilitate the availability and take-up of discounted medicines for the poorest in a manner that is fair, efficient and sustainable. We recognize the complexity of increasing access to medicines in developing countries which, among other factors, depends on affordable prices. We welcome pharmaceutical companies' voluntary long-term commitments to providing essential medicines at substantially discounted prices to developing countries and strongly encourage further efforts, including through supply competition. We will also work with developing countries to encourage greater uptake of such offers of free and discounted drugs, as are now being made. (G8, 2003: 3.1)

Notably, the 2006 G8 Summit in St. Petersburg, Russia, established a summit record through setting 64 commitments in the area of health and dedicating 84 paragraphs to health issues (Kirton, Roudev, and Sunderland, 2007: 193). In the Fight Against Infectious Disease statement released at St. Petersburg, the G8 noted the relationship between access to medicines and develop-

ment and the possibility of WTO members using the flexibilities within the TRIPS Agreement and the compulsory licensing decision of August 2003, and they called on WTO members to consider the elimination of import tariffs and non-tariff barriers on medicines to increase access to medicines. Perhaps such increased attention can be attributed to the "increasingly equal vulnerability of each G8 member to a new generation of infectious disease" (Kirton, Roudev, Sunderland, and Kunz, 2008: 172).

The impact of the G8's increased attention to global health governance issues has not always been favourable. Perspectives differ considerably, running the gamut from "fatal indifference" (Labonte, 2002, quoted in Kirton et al., 2008: 170), "the global health governor of last resort" (Price-Smith 2001, 2002, quoted in Kirton et al., 2008: 173), and "the emerging center of twenty-first century global governance" (Bayne, 2000, 2001, quoted in Kirton et al., 2008: 172).

Despite these differing views, G8 scores on compliance to health-related commitments are not impressive. Between 1996 and 2005, the average G8 compliance scores on all health-related issues[10] was +47.5%,[11] with a wide variation in years, ranging from an impressive +80% in 2003 to only +26% in 1998 and 2002 to (Kirton et al., 2008: 173). In the same period, there was considerable variation in compliance to specific issues. While compliance to issues related to sudden outbreaks of disease was high, such as an average of +78% in the case of SARS, issues related to public health, such as drugs/medicine, scored an

[10] Health-related issues include public health, human health and well-being, pharmaceuticals, medicines, infectious diseases, health-related international organizations, ageing, drug use, drug conventions, potable water, biotechnology, and bio-terrorism as it relates to human health.

[11] On a scale of -100% to +100% using the G8 Research Group's compliance coding system.

average compliance of only +45% and development scored a dismal average of 0% (Kirton et al., 2008: 173). Kirton and his colleagues noted that the G8 "performs better within a biomedical model aimed at responding to acute outbreaks of diseases such as SARS, not at proactively addressing health's socioeconomic determinants and underdevelopment's root causes" (2008: 196).

Catalyst, not Cure

The above analysis weakens the argument that the G8 is the best-suited international institution for providing a cure to ailing global health governance through ensuring greater multi-level policy coherence in trade, development, and public health. However, three unique governance mechanisms of the G8 make the group a potentially powerful catalyst to bring about the necessary innovation in global health governance. These governance mechanisms are elaborated below with an assessment of their potential use as a catalyst for greater multi-level policy coherence in trade, development, and public health at the 2008 G8 Summit in Hokkaido, Japan.

Mutual Accountability

The G7 originated in 1975 as an informal meeting of heads of state or government of the most industrialized economies in the world, a forum at which leaders could talk "frankly and without inhibitions" (Bayne, 2000: 21). It became immediately apparent that the coordination of international economic and monetary policies required both co-operation and mutual accountability of domestic policies. Annual G7/G8 summits served to pressure the individual member governments to "resist the pressure for inward-looking policies" (Bayne, 2000: 22). Thus, the governance mechanism of relying on mutual accountability and co-operation could serve to encourage individual G8 mem-

bers to follow the good practices of other members in developing and implementing policies.

For example, when the average compliance scores of health-related issues are broken down by country, a different, more positive, image of G8 compliance emerges. Between 1996 and 2005, variance in compliance ranged from such high scores of +81% for the European Commission[12] and +72% for Britain to low scores of +21% for Italy and +4% for Russia (Kirton et al., 2008: 173).

Serving as the host country offers individual G8 members the opportunity to propose innovative domestic and global policies in their targeted issue areas. As host of the G8 in 2005, Britain was able to persuade the other members to agree to double aid to Africa by 2010 and increase aid to all developing countries, with one aim being to get almost universal access to AIDS medicines by 2010 (G8, 2005). Although G7 countries increased their overseas development assistance (ODA) from US$58 billion in 2004 to US$80 billion in 2005, progress slowed to US$75 billion in 2006 (Jessee, 2007: 3). During a speech at the 2008 World Economic Forum annual meeting in Davos, Japanese prime minister Yasuo Fukuda announced that as hosts of the G8 Summit taking place in Hokkaido from 7-9 July 2008, Japan will place health issues, in the context of Africa and development, as one of three priority topics of the summit (The Ministry of Foreign Affairs of Japan, 2008). To show its commitment to this issue, Japan is planning to create a fund of 110 million yen to increase its efforts to "help African countries protect and make better use of intellectual property" (Karube, 2008).

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[12] The European Commission represents the EU in the G8, in particular the non-G8 members. On matters of trade, since the European Commission negotiates for the EU, it speaks for the entire membership.

Through mutual accountability, members with high compliance could place pressure on the others to fulfill their G8 health commitments at the domestic, regional, and global level in order to ensure policy coherence.

Delegation

Beginning in 1998, in response to a host of new policy and political issues placed on the summit agenda due to globalization, the G8 increasingly delegated follow-up activities to other international institutions, the private sector, and civil society organizations in addition to the relevant ministries. At the same time, they began to invite a number of developing countries to participate in outreach sessions at the G8 summits. This broad, multi-stakeholder approach has served as a successful catalyst for effective innovation in the governance of several policy areas including public health.

For example, the 2000 G8 Summit in Okinawa set the stage for the creation of a partnership with WHO and other relevant international organizations, industry, academics, and NGOs from the G8 and African countries in order to meet Goal 6 of the MDGs, which includes working toward making "key drugs, vaccines, treatments and preventive measures more universally available and affordable in developing countries" (G8, 2000: paragraph 30). This partnership sparked the establishment of the Global Fund to fight AIDS, Tuberculosis, and Malaria[13] that UN Secretary General Kofi Annan called for in April 2001.[14]

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[13] The Global Fund acknowledges that its roots are based in the 2000 G8 Summit in Okinawa (see: http://www.theglobalfund.org/en/about/road/)

[14] See Kofi Annan's statement at: http://www.un.org/News/Press/docs/2001/SGSM7779R1.doc.htm

The 2008 Hokkaido G8 Summit has the potential to provide a similar catalyst for greater coherence on global public health policy. At the 2008 World Economic Forum annual meeting Prime Minister Fukuda also stated that there was a need for stronger co-operation in the area of global health if the MDGs were to be met on time, and that "[the leaders] must formulate a framework for action to raise the overall level of the health care system, with the participation of all relevant stakeholders, such as international organizations and health policy experts with expertise and experience, NGOs active in local communities, civil society groups and private sector entities" (The Ministry of Foreign Affairs of Japan, 2008). A G8 Health Experts' Meeting on 14-15 January 2008 and the Fourth Tokyo International Conference on African Development[15] held 28-30 May contributed to the content of the Hokkaido G8 Summit.

Ratchet Effect

Major annual meetings of key international institutions and organizations such as the World Economic Forum (annual meeting held in January), the Organisation for Economic Co-operation and Development (annual meeting held in May or June), the G8 (summit held in June or July), the International Monetary Fund and World Bank (spring meetings held in April and annual meetings held in September or October), and the United Nations (annual meeting held in September) are scheduled within weeks of each other in order to increase the momentum on specific topics of global concern, thus providing a ratchet effect to global governance. Policy makers and negotiators use these meetings

[15] For more information on TICAD IV, see http://www.undp.org/ticad2/news-20080319.shtml

as deadlines as well as sources of policy direction and decision making[16]. Given that the G8 is the only such institution to meet at the level of head of state or government, it provides critical political leverage to global policy coherence.

The Hokkaido G8 Summit, focusing in part on the MDGs of combating HIV/AIDS, malaria, and other infectious diseases, reducing child mortality, and improving maternal health is part of a "Year of Action" on the MDGs, launched by UN secretary general Ban Ki-moon and UK prime minister Gordon Brown at the World Economic Forum in Davos in January 2008. The summit will be preceded by a Downing Street Summit in the UK in May and an EU Summit in June that will focus on new ideas and resources for meeting the MDGs. This topic will be further discussed at a high-level UN meeting on the MDGs in September (The Ministry of Foreign Affairs of Japan, 2008).

Keys to strengthening global health governance include creating and sustaining political support among the countries of the G8 and key African countries, and policy support among the relevant international organizations, industry, and civil society for real commitment to creating greater multilateral policy coherence among trade, development, and public health. Despite the fact that G8 and African leaders face different challenges given the state of development in their countries, this high-level institutional sequencing of meetings and the setting of action plans with annual reviews of progress keep these important policy issues on both the political and public radar, and as such will assist in a "ratcheting up" of the issues.

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[16] For an excellent discussion on the G8's placement within the pyramidal structure of the global trade regime, see Cohn, Theodore H (2002). *Governing Global Trade: International Institutions in Conflict and Convergence*. Aldershot: Ashgate.

5. Recommendations for Enhancing Multi-level Policy Coherence

The analysis in this paper suggests that rather than serving as a cure for the current state of global health governance, the G8 best serves as a catalyst for better policy and political decisions. Given this conclusion, the following recommendations are offered:

The global health governance system must experience a paradigm shift

The current traditional global health governance system of international organizations, states, and private and public non-state actors that focus primarily on policy at the domestic and international levels requires a transformation to take into account the inter-linkage between trade, development, and public health and the growing regional dimension of global public health.

States must follow coherent, consistent trade, development, and public health policies

Although global governance consists of many private and public actors, states remain the primary actor, given that they offer direction to intergovernmental organizations, regulate their industries, and negotiate and implement binding agreements in trade, development, and health. Given their role, they must also recognize their responsibility to the global health system and consistently practice coherent policies with respect to trade, development, and public health in order for global governance to be effective. In the case of the US, although the 2007 Bipartisan Trade Deal was a welcome move, given that it mandated revisions of several TRIPS-plus IPR provisions within four US FTAs, there are several US-negotiated FTAs that still contain these provisions. Thus, the US is still not respecting the

WTO Declaration on Public Health it signed in 2001 and as is called for in the US Trade Act of 2002. To show leadership within the G8 as well as within the international community, the US must comply with its commitments at the multilateral, regional, and domestic level. Thus, the US should ensure that all existing and future US FTAs fully comply with the spirit and letter of the Public Declaration.

The G8 must use its potential as a catalyst to a greater degree

Because its membership includes the majority of the most developed countries in the world, the G8 must use its unique governance mechanisms, including mutual accountability, delegation, and its ratchet effect to serve as a catalyst for more coherent policy in public health in a more consistent and effective manner. The G8 should focus on increasing compliance within the Group of 8 on health-related issues, particularly meeting financing commitments, and providing innovative ideas and initiatives to ensure that multi-level policy coherence in trade, development, and public health leads to stronger global health governance. The G8 could call for the creation or improvement of existing, long-term multi-level partnerships of health experts and health care workers, government officials, pharmaceutical companies, foundations, and civil society to develop practical solutions to existing public health challenges. However, such partnerships will need to be coordinated under a common mechanism, so as to avoid duplication and confusion, and be adequately funded by both public and private sources to improve health care systems and build human and productive capacity in developing countries.

Annex I: Millennium Development Goals

The Millennium Development Goals
(including targets and indicators for public health and development)

Goal 1	**Eradicate extreme poverty and hunger**		
Goal 2	**Achieve universal primary education**		
Goal 3	**Promote gender equality and empower women**		
Goal 4	**Reduce child mortality**		
	Target 5	Reduce by two-thirds the mortality rate among children under five	
		Indicator 13	Under-five mortality rate
		Indicator 14	Infant mortality rate
		Indicator 15	Proportion of 1-year-old children immunized against measles
Goal 5	**Improve maternal health**		
	Target 6	Reduce by three-quarters the maternal mortality ratio	
		Indicator 16	Maternal mortality ratio
		Indicator 17	Proportion of births attended by skilled health personnel
Goal 6	**Combat HIV/AIDS, malaria and other diseases**		
	Target 7	Halt and begin to reverse the spread of HIV/AIDS	
		Indicator 18	HIV prevalence among 15-24 year-old pregnant women
		Indicator 19	Condom use rate of the contraceptive prevalence rate and population aged 15-24 with comprehensive correct knowledge of HIV/AIDS
		Indicator 20	Ratio of school attendance of orphans to school attendance of non-orphans
	Target 8	Halt and begin to reverse the incidence of malaria and other major diseases	
		Indicator 21	Prevalence of death rates associated with malaria
		Indicator 22	Proportion of population in malaria risk areas using effective malaria prevention and treatment measures
		Indicator 23	Prevalence of death rates associated with tuberculosis
		Indicator 24	Proportion of tuberculosis cases detected and cured under directly-observed treatment short courses
Goal 7	**Ensure environmental sustainability**		
Goal 8	**Develop a global partnership for development**		
	Target 12	Develop further an open, rule-based, predictable, non-discriminatory trading and financial system. Includes a commitment to good governance, development, and poverty reduction – both nationally and internationally	
	Target 13	Address the special needs of the least developed countries. Includes: tariff and quota free access for least developed countries' exports; enhanced program of debt relief for HIPCs and cancellation of official bilateral debt; and more generous ODA for countries committed to poverty reduction	
	Target 14	Address the special needs of landlocked countries and small island developing states	
	Target 15	Deal comprehensively with the debt problems of developing countries through national and international measures in order to make debt sustainable in the long term	
	Target 16	In cooperation with developing countries, develop and implement strategies for decent and productive work for youth	
	Target 17	In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries	

Target 18	In cooperation with the private sector, make available the benefits of new technologies, especially information and communication	
	Indicator 32	Net ODA as percentage of OECD/DAC donors' gross national product
	Indicator 33	Proportion of ODA to basic social services
	Indicator 34	Proportion of ODA that is untied
	Indicator 35	Proportion of ODA for environment in small island developing states
	Indicator 36	Proportion of ODA for transport sector in landlocked countries
	Indicator 37	Proportion of exports admitted free of duties and quotas
	Indicator 38	Average tariffs and quotas on agricultural products and textiles and clothing
	Indicator 39	Domestic and export agricultural subsidies in OECD countries
	Indicator 40	Proportion of ODA provided to help build trade capacity
	Indicator 41	Proportion of official bilateral HIPC debt cancelled
	Indicator 42	Total number of countries that have reached their HIPC decision points and number that have reached their completion points
	Indicator 43	Debt service as a percentage of goods and services
	Indicator 44	Debt relief committed under HIPC Initiative
	Indicator 45	Unemployment of 15-24 year-olds, each sex and total
	Indicator 46	Proportion of population with access to affordable, essential drugs on a sustainable basis
	Indicator 47	Telephone lines and cellular subscribers
	Indicator 48	Personal computers in use and internet users

HIPC – Heavily Indebted Poor Countries;
ODA – Overseas Development Assistance
Source: UNDP, 2008

Annex II: Declaration on the TRIPS Agreement and Public Health

Declaration On The Trips Agreement and Public Health
Adopted on 14 November 2001

1		We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
2		We stress the need for the WTO Agreement on Trade-Related Aspects of intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
3		We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
4		We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.
5		Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
	a	In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
	b	Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
	c	Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
	d	The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.
6		We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.
7		We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

Source: WTO, 2001

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CIGI was founded in 2002 by Jim Balsillie, co-CEO of RIM (Research In Motion), and collaborates with and gratefully acknowledges support from a number of strategic partners, in particular the Government of Canada and the Government of Ontario. CIGI gratefully acknowledges the contribution of the Government of Canada to its endowment Fund.

Le CIGI a été fondé en 2002 par Jim Balsillie, co-chef de la direction de RIM (Research In Motion). Il collabore avec de nombreux partenaires stratégiques et exprime sa reconnaissance du soutien reçu de ceux-ci, notamment de l'appui reçu du gouvernement du Canada et de celui du gouvernement de l'Ontario. Le CIGI exprime sa reconnaissance envers le gouvern-ment du Canada pour sa contribution à son Fonds de dotation.

To learn more about CIGI and IGLOO please visit:
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