Improving Access to Essential Medicines: How Health Concerns can be Prioritised in the Global Governance System

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This paper discusses the politics of access to essential medicines and identifies 'space' in the current system where health concerns can be strengthened relative to trade. This issue is addressed from a global governance perspective focusing on the main actors who can have the greatest impact. These include developing country coalitions and citizens in developed countries through participation in civil society organisations. These actors have combined forces to tackle this issue successfully, resulting in the 2001 Doha Declaration on Public Health. The collaboration has been so powerful due to the assistance of the media as well as the decision to compromise with pharmaceutical companies and their host countries. To improve access to essential medicines, six C's are needed: coalitions, civil society, citizenship, compromise, communication and collaboration.

Access to Essential Medicines: The Debate

Patents are often viewed as a technical issue, one to be discussed and contested by intellectual property lawyers who are familiar with the complex language used in drafting agreements and briefs. However, as the past 10 years have shown, patents are actually a critical health issue and, as Pogge (2007) has argued, an important moral issue of our time. The agreements made at the global level within the World Trade Organisation (WTO) and in bilateral trade negotiations have enormous local implications, especially among the global poor.

In this paper, I discuss the politics of access to essential medicines and identify 'space' in the current system where change can be made. I would like to start by stating the obvious problem: the current state of access to essential medicines among the global poor is unacceptable. Every year there are over 18 million preventable deaths and tens of millions more cases of increased morbidity due to poverty-related causes and arguably the unavailability of essential medicines. Why in a world of plenty do we still have so much suffering? This leads us to a moral question: what are our moral duties to those who are suffering from preventable and treatable illnesses due to the unavailability of pharmaceuticals, or, when they do exist, a lack of access to them? The current situation constitutes a violation of the human rights of millions of the world's poorest people.

At a global level, there is a systematic weakness of health concerns relative to trade and tensions between the governance of trade and health (Lee *et al.*, 2008). For example, human rights and health activists have argued that patent protection prevents access to essential medicines, resulting in unnecessary, excessive and unjust mortality and morbidity. However, this argument has been dismissed by pharmaceutical industry representatives and their host countries, who have argued that patent protection, such as that afforded by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),¹ is necessary to incentivize research and thus save lives in the long term. In terms of patent protection barring access to drugs, they point to research such as Attaran's (2004) article, which argues that patent protection for AIDS medications has little effect on the distribution of drugs, to argue that it is other factors in developing countries that result in limited access to essential medicines.

The patent regime notwithstanding, there are structural and wider societal factors in developing countries that impede access to medicines. Morbidity and mortality are often the result of underlying social inequality, poverty, gender inequality, caste/class discrimination and lack of access to clean water and adequate sanitary facilities. Thus there is an argument to be made for paying attention to the forces that produce and aggravate the social conditions that impede access to essential medicines. Indeed, this line of argument has been used by

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pharmaceutical companies, lobbyists and the US government to stall action on generic drug production and uphold patent protection, such as that afforded by TRIPS.

There is no question that structural factors are important. Most developing countries do need better health systems and infrastructure, more health workers, clean water and proper sanitation and better institutions. They do need equitable economic growth, job creation and poverty reduction. Few would question this. But the importance of these factors does not reduce the significance of the barriers to access to essential medicines at reasonable prices that are created through patent laws. The focus on structural factors in developing countries is often an excuse for the lack of progress in trade negotiations. In addition, when access to essential medicines is blocked by two barriers (patent protection and structural factors in developing countries), we cannot absolve one of responsibility on the basis that the other exists. This would provide perverse incentives for those who would block attempts to address structural factors to ensure that there is a second barrier to patent protection also in place. And it would provide no moral incentives to remove either barrier (as each is innocent of the harm they together produce).

Barriers to improving access to essential medicines exist at different levels, including research on one hand and production and pricing on the other. In terms of research, Pogge (2007) has proposed a complementary patent arrangement called the Health Impact Fund (HIF), which focuses on incentivizing pharmaceutical companies to develop drugs for diseases that predominantly afflict the poor. As Ravvin (2008) notes, 'Under this plan, instead of receiving profits from selling patented drugs at high monopoly prices, innovators could opt to register any newly patented medicine with the HIF, which would provide a guaranteed payment stream in proportion to the incremental impact of the innovative drug on the global burden of disease (GBD) during its first 10–12 years on the market.' I return to this proposal later in this paper. In terms of pricing and production, I will focus on the room in the current system for health concerns to be prioritised. This issue is addressed from a global governance perspective focusing on the main actors who can make a difference. These include developing country coalitions and citizens in developed countries.

The Role of Developing Countries

I turn now to examine the important role that developing countries can play in the prioritisation of health relative to trade concerns. It is first important to understand the

inner workings of the WTO. As Patel (2007) describes, despite the existence of a voting structure, WTO decisions are reached through 'consensus' within restricted inner-group meetings, known as 'Green Room' meetings. Historically, the four members included in these meetings were USA, Japan, the EU and Canada. Because of this informal and exclusive governance arrangement, the WTO has been criticised for its lack of transparency and marginalisation of developing country concerns. An example of this marginalisation is TRIPS, where organised and coordinated intellectual property stakeholders, most significantly large pharmaceutical companies, came together to press for certain conditions such as stringent intellectual property rights in all countries regardless of their state of development. (It should be noted that private interests are of course informally represented at WTO negotiations; officially, negotiations are conducted among states.)

Why did developing countries, which had the most to lose, agree to TRIPS? Some have explained the agreement of developing countries to TRIPS by pointing to the elites that govern them, who do not always represent the needs of the poorest citizens. While I recognize the validity of this argument in some cases, I argue that government should nonetheless be the key actor in development if its legitimacy is derived from democracy and an electoral process. Thus I take the perspective that developing country governments with democratic legitimacy should have the authority and capacity to represent their countries' interests in trade negotiations, and should be able to do so on fair terms with wealthy countries. In brief, ownership and control of trade negotiations by developing country governments are important for three distinct reasons: effectiveness and sustainability, democracy and self-determination and the alignment of accountability with effectiveness (such that those who make the key decisions also bear the risk if policies have detrimental effects).

Pogge (2007) offers an alternative explanation. He argues that most poor countries lacked the bargaining power to resist the conditions of TRIPS that were imposed by rich countries. This situation raises the question of how relatively weak developing countries can negotiate on a fair basis with the powerful, developed states within the WTO. Using a political-economic perspective, we can choose a country that has achieved a certain level of success in pharmaceutical trade negotiations, such as India, and try to understand what factors facilitated the process. Drawing on interviews with Indian government officials involved in the negotiations, I identify four main factors: financial independence from wealthier states, a clear plan, strong leadership and technical expertise in intellectual property law.²

Countries that enter trade negotiations without these four elements face a significant disadvantage. This can be overcome through developing countries organising and forming a coalition and pushing forward their collective agenda. Developing country coalitions have built and used coalitions to improve their bargaining power.³ As Patel (2007) describes, this pooling of bargaining resources has improved the technical and lobbying capacity by which developing countries engage in the WTO. These coalitions are highly visible, formalized and coordinated and focus on working within the WTO and existing trading structures to proactively engage in the negotiation process with the purpose of improving outcomes for developing countries.

Patel (2007) outlines three benefits of developing country coalitions. First, countries can share the costs of negotiating in the WTO. Developed countries have many negotiators based in Geneva, while developing countries have much fewer. For example, Carolyn Deere has noted that the USA, Canada, Japan, and the EU have roughly two Geneva negotiators per 10 million citizens while developing countries have just one. These numbers do not capture the fact that many of the delegates from developing countries are also responsible for covering other international organisations that are based in Geneva (e.g. World Intellectual Property Organisation, International Labour Organisation). Second, coalitions enable collaboration among countries so that they are able to compensate for their individual capacity limitations by sharing the tasks of technical and legal analysis. Third, coalitions can increase representation of developing countries. In 2004, 33 developing countries that were WTO members had no permanent representatives to the WTO based in Geneva, and so were unable to be present at a number of trade negotiations. More negotiations can be monitored when formal delegates are elected to represent groups of developing countries (e.g. African Group; African, Caribbean and Pacific Group of States (ACP); Least Developed Countries Group (LDC)).

I would add a fourth benefit of developing country coalitions. By aligning with emerging countries such as China, India and Brazil, less powerful countries can better handle the bullying tactics of certain developed states. I would like to elaborate on the final point, as it is critical to understanding the implementation of TRIPS. While most parties involved have seen TRIPS as a maximum standard of compliance, the USA has viewed it as a minimum. The USA has used its power to enforce TRIPS and bully countries into complying. Beyond this, the USA has used bilateral free trade agreements to extend the reach of TRIPS and increase patent protection beyond the provisions of TRIPS; these agreements are referred to

as TRIPS-plus. Caroline Thomas (2002: 255) quotes an NGO staff member in Washington, DC:

The problem for developing countries is not whether the compulsory licensing of pharmaceuticals is legal, because it clearly is legal. It is the political problem of whether they will face sanctions from the U.S. government, for doing things that they have a legal right to do, but which the U.S. government does not like.

Similarly, Ralph Nader and James Love have spoken about the 'weight of the US power, short of military warfare, on South Africa to prevent that country from implementing policies to obtain cheaper sources of essential medicines' (cited in Thomas, 2002: 256). For example, in 1997 and 1998, Thailand, in the face of the HIV/AIDS crisis, attempted to use TRIPS articles 30 and 31 to pursue compulsory licensing of generic medicines. However, Thailand dropped these plans when threatened with sanctions by US trade officials (supported by the lobbying organisation PhRMA, the Pharmaceutical Research and Manufacturers of America).

The Role of Citizenship

The other main group of actors, citizens in developed countries, are especially important in light of the attitudes that developed countries take towards trade negotiations and enforcing trade agreements. The main multilateral trade institution, the WTO, consists of member-states. The government of each state, at least the democratic ones (which also happen to include the developed countries), are accountable to their citizens. Thus, those of us living in the wealthier countries have considerable influence over our governments' decisions and are therefore to a certain extent responsible for its actions, regardless of whether they take place in a multilateral forum or through bilateral agreements.

How can an individual influence his or her government's trade policy? Citizens can organise and form consumer groups, such as Knowledge Ecology International run by James Love, or join and financially support civil society organisations (CSOs) advocating for access to essential medicines. Citizens can write to their senators, representatives, or members of Parliament arguing why a change in foreign policy is necessary. Perhaps most effectively, citizens can make health and human rights a key electoral issue and apply pressure during presidential and senatorial campaigns. The upcoming 2008 US presidential election provides an opportunity for citizens to lobby for access to essential medicines as candidates attempt to avoid bad press.

Doha Declaration on TRIPS and Public Health

Doha Declaration on TRIPS and Public Health

Developing countries and citizens in developed countries represented by CSOs working together can increase the voice and interests of those most in need of affordable medicines. This was demonstrated in November 2001 when the WTO adopted the Doha Declaration on TRIPS and Public Health. In this agreement, a coalition of developing countries sought explicit assurance that they would not be subject to WTO penalties under TRIPS for addressing certain health crises by issuing compulsory licenses and extending for 10 years the deadline by which least developed members must provide patent protection for pharmaceuticals (Odell and Sell, 2006). How were the developing countries able to achieve this despite the powerful opposition from pharmaceutical companies and their host countries?

Four key factors can be identified (Odell and Sell, 2006). First, intellectual property was framed as a public health issue about saving lives by civil society organisations, which captured the attention of mass media in industrialised countries. CSOs, such as MSF (Médecins Sans Frontières), TAC (Treatment Action Campaign), ACT UP Paris, Oxfam GB and Health Action International, pushed the issue to the forefront, indicating the role that these organisations and networks can play in supporting the agenda of developing countries and lobbying on their behalf. In addition, citizens lobbied their governments and gained the attention of prominent officials. During the 2000 US elections, when Al Gore announced he was running for president, health activists interrupted his speech chanting 'Gore's Greed Kills.' The media picked up this story, and then the White House reached out to activists and started discussions.

Second, the developing country coalition did not fragment and pursued a common objective in WTO negotiations. Even in the face of US concessions to the African Group in the hope that it would withdraw, the coalition stayed together. Third, the coalition was large, including the African Group, Brazil, India, Pakistan, Bangladesh, Indonesia, Thailand, Sri Lanka, Philippines and 11 other Latin American and Caribbean states, and thus could not be easily dismissed. The inclusion of Brazil was important as the country was already a leader in the generic production of antiretrovirals and could play a key role in the negotiations. Fourth, the coalition eventually made a compromise and went after what was achievable given the existing trading structures, not what was ideal. While perhaps imperfect from an ideal moral perspective, com-

promise was arguably necessary to achieve agreement on the Declaration, which was highly preferable to no Declaration at all. One can see these four factors as forcing the pharmaceutical manufacturers and their home governments to compromise and agree to the Declaration.

Mixed News Since 2001

Despite the general disappointment with the patchy implementation of the 2001 Declaration (Love, 2006), there has been some positive news from individual developing countries on the prioritisation of health. For example, Thailand and India have become strong examples for what can be achieved for other developing countries. In November 2006 the government of Thailand announced that it would issue a compulsory license to the Government Pharmaceutical Organisation of Thailand so that the company could produce the AIDS drug efavirenz (Stocrin), which was still under patent by Merck. Then, in January 2007, the government of Thailand issued a compulsory license on patents for clopidogrel bisulfate, a heart disease drug, as well as compulsory licenses on patents on the AIDS drug sold by Abbott under the name of Kaletra.

In addition, in 2006, India rejected Novartis' patent application for the cancer drug Gleevec. Under Indian law, patents are only given for medicines invented after 1995, or for new and more efficacious versions of older drugs. The law in effect upholds scope for the production of generic medicines. India rejected the patent application because the drug that Novartis wanted to patent was not more efficacious than older versions. Novartis challenged the decision in a court in Chennai as the company argued that the decision, and the criteria used to make the decision, violated WTO law and could set a precedent that would make it very difficult to patent new drugs. In 2007, the court ruled against Novartis and in favour of Indian law, and more importantly for those concerned with public health, in favour of public health interests over intellectual property law. The Novartis case has set an important precedent. GlaxoSmithKline recently withdrew patent applications for its antiretroviral drugs Abacavir and Trizivir in India due to concerns about Novartis' patent rejection and about challenges to its patent applications by CSOs MSF and I-MAK. GlaxoSmithKline thought it better to withdraw the applications rather than receive a rejection because a rejection could weaken the country's chances of receiving patents in other developing countries.

Pharmaceutical companies have argued that facilitating compulsory licensing and patent rejection by certain developing countries undermine incentives for research

in neglected diseases. GlaxoSmithKline states, 'Use of compulsory licensing... would significantly undermine the benefits to be gained from patents (which are real) without having a significant beneficial impact on access.'⁴ These fears, however valid, provide more reason to favour a systematic solution to this problem, such as that provided by the Health Impact Fund (Ravvin, 2008).⁵ The implementation of this proposal would go some way toward abating fears that compulsory licensing and patent rejection will decrease the amount of research into neglected diseases.

The Way Forward

Despite the agreement reached on the 2001 Doha Declaration on Public Health, as of the end of 2007, nothing agreed upon has yet been launched, and USA is increasingly turning to bilateral agreements outside the WTO in order to thwart the power of negotiating coalitions. These bilateral agreements erode the gains made in the 2001 declaration. In addition, the use of bilateral agreements such as Economic Partnership Agreements (EPAs) has resulted in negotiations taking place outside the WTO. These agreements have been notoriously difficult for the WTO and CSOs to monitor. The politics of trade negotiations have therefore changed to preserve the negotiating advantages of developed countries through the use of bilateral agreements that circumvent the WTO.

What is the way forward? To improve access to essential medicines, six C's are needed: coalitions, civil society, citizenship, compromise, communication and collaboration. All six elements came together when the 2001 Doha Declaration was agreed upon. First, developing countries must form a coalition that comes together to achieve a very specific objective and does not fragment. Second, CSOs committed to health issues must continue to push the issue onto the political agenda. Third, citizens in developed countries need to pressure their governments to prioritise health concerns through lobbying, protesting and supporting CSOs. Fourth, the various stakeholders must compromise to a certain extent so that progress can be made. Fifth, health activists must communicate to the media, so that the media can frame the issue of access to essential medicines in an appealing manner. Finally, developing countries, CSOs and citizens in developed countries must collaborate to ensure that the barriers to access to essential medicines are overcome.

I conclude this paper by focusing on the issue of power: who gets what, when and how. As citizens we must think about what part each of us will play as we move forward into the twenty-first century. We need to think about who has power, how they use it and how we, as concerned

actors in our respective roles as academics, practitioners, policy-makers, activists and citizens, can ensure that our governments and international institutions function with attention to the moral duty to reduce the obstacles to access to essential medicines.

Notes

1. For details on TRIPS, see http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm
2. India is of course unique as it has a large population and economic independence from donor countries.
3. This analysis draws on the important work of Mayur Patel (2007) as well as Susan Sell and John Odell (Odell and Sell, 2006; Sell, 2002).
4. http://www.iprcommission.org/graphic/Views_articles/GlaxoSmithKline.htm
5. <http://www.patent2.org/index.html>

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