The Quest for Global Governance in Intellectual Property and Public Health: Structural, Discursive and Institutional Dimensions

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Abstract

The contest between competing knowledge networks is raging in the World Trade Organization (WTO) over diverse interpretations of the Agreement on Trade-Related Aspects of Intellectual Property Rights. The sharpest conflict is between trade and public health. To what extent can persuasion and principled argument can be a potent asset for the weak to bring about desired change? How can the legal debate over the boundaries of the WTO and the extent to which declarations, laws, and regulations promulgated in other venues are relevant to WTO deliberations help developing countries devise strategies to press their concerns more effectively? Given sharply asymmetrical power relationships, what are the prospects for achieving outcomes that better balance public health and commercial concerns? This paper argues that principled argument has the potential to alter actors' interests and outcomes. While coercion is a viable weapon of the strong, principled argument can be a potent asset for the weak to bring about desired change. This is especially the case when such discursive strategies are coupled with the strategic use of a variety of institutions.

Increasingly, public health policy has had to interact with environmental, trade, economic and intellectual property policy. Just considering the intersection between public health, trade, and intellectual property, governance in public health is complicated by the diverse institutions involved, including the World Health Organization (WHO), the International Monetary Fund (IMF), the World Bank (WB), the World Trade Organization (WTO), and the World Intellectual Property Organization (WIPO). Global governance means devising, implementing, and enforcing policies in a way that accomodates a broad range of stakeholders and publics. Challenges to effective global governance of public health issues include trade pressures, multi-layered governance (i.e., local, national, bilateral, regional, international), the complexity of health policy jurisdiction across multilateral organizations, the simultaneous development of hard and soft law in diverse venues with conflicting mandates and values, economic coercion, and unequal access to resources and institutions. Among the central features of the quest for global governance in intellectual property and public health are the blurring lines between public and private, the increasing role of the private sector in public policy making, growing global inequality, constricted autonomy for the weak, and the inappropriateness of "one-size-fits-all" policies for diverse contexts.

The development of global public health policy is shaped by developments in three dimensions: structural, discursive, and institutional. The structural dimension is characterized by glaring economic and political power asymmetries between developed and developing countries. The structural dimension has also fostered the ascendance of the global life sciences industries in public health policy making. Battles between commercial and social agendas in public health are hardly waged on a level playing field. Given these asymmetries, what are the possibilities available to the weak through discursive and institutional strategies? The current environment presents dangers and opportunities. The "weak" must become adept at playing the multi-level, multi-forum governance game. As Helfer has pointed out, governments, non-governmental organizations (NGOs) and commercial actors are engaging in "regime shifting" that reveals "an acute awareness by government officials, international secretariats, and non-state actors of the fluidity of lawmaking processes, and reveals such actors' keen ability to assess the comparative institutional advantages offered by different negotiating fora for achieving particular goals" (Helfer, 2003: 64). Deftly advancing different types of arguments and mobilizing different players in a variety of international institutions, these actors have begun to alter rules and procedures that affect public health. What are the relationships between various international organizations? What perspectives do they promote? Who is defining and shaping these perspectives? When these perspectives conflict, what perspective prevails and why? Are international organizations roughly equal, or do they exist in strictly hierarchical relation to each other? How malleable are these relationships? Can discursive and institutional strategies alter these relationships?

Global intellectual property rules in the World Trade Organization (WTO) emerged from a vigorous corporate campaign to link intellectual property and trade. This campaign employed economic expertise, effective discursive strategies, and forum shifting to

persuade the U.S. government to redefine its interests in intellectual property protection. The result was a dramatic global expansion of protections for rights holders and penalties for violators of intellectual property rights. In the wake of the WTO Agreement on Trade-Related Aspects of Intellectual Property (TRIPS hereafter) a vigorous civil society campaign has mobilized to protest this expansion of rights, particularly in the face of the HIV/AIDS pandemic. Arguing that intellectual property rights should be construed as a public health issue, rather than a trade issue, this civil society campaign has scored some victories in challenging the corporate perspective. This group seeks to limit the expansion of intellectual property rights and reduce such rights for essential medicines in an effort to contain costs and increase access. TRIPS opponents, consisting of consumer groups, NGOs, and a number of developing country governments, have used “counter-experts” to challenge the trade-based conception of intellectual property rights in favor of a public health perspective. The corporate TRIPS architects have been forced to respond to this challenge and engage the debates of the civil society groups.

The contest between these competing knowledge networks is raging in the WTO over diverse interpretations of TRIPS. Moreover, it is animating related deliberations in the WHO and WIPO. Governance in this area is complicated by the fact that different groups are scoring “victories” in some venues, while opposing groups are scoring “victories” in other venues. For instance, while the access to medicines agenda has moved forward in both the WHO and the WTO, WIPO is moving forward with the Substantive Patent Law Treaty deliberations which threaten to reverse any gains achieved in other forums. The United States, at the behest of non-generic pharmaceutical firms, is pursuing an aggressive course of bilateral and regional intellectual property and investment agreements that further undermine any broader gains for developing countries in the throes of the HIV/AIDS crisis.

This paper examines structural, discursive, and institutional dimensions of the quest to balance public health, trade, and intellectual property. These dimensions help to highlight both the obstacles to and opportunities for advancing public health concerns over competing values when necessary. The international organizations dealing with public health and intellectual property are embedded in a broad structural context of unevenly distributed political and economic power. "Policy content has been closely aligned with global shifts in power and influence among key policy actors" (Buse et. al. in Lee et. al eds 2002: 256). The structure of the organizations varies in reflecting these inequalities. For example, an organization like the IMF mirrors unequal power relationships with weighted voting according to contribution, whereas the United Nations General Assembly’s one-nation one-vote system formally obscures these inequalities. Furthermore, one of the major developments in the health sector has been "the rapid growth of public-private partnerships in recent years [that] has given the private sector unprecedented entree into policy-making circles in national governments and key organizations such as WHO, UNICEF and the World Bank" (Buse et. al. in Lee et. al. eds 2002: 262). Access to and participation in various organizations is uneven, and the costs of participating in venues such as the WTO can be prohibitive for those without substantial resources.

Discursive dimensions are also important. Information plays an important role in the policy process. However, information is not knowledge (Comor, 2001). Given bounded rationality, actors employ filters to identify useful and interesting information (Tversky and Kahneman, 1981; Jones, 2001). People transform information into knowledge by employing different normative frames. Frames are "specific metaphors, symbolic representations and cognitive clues used to render or cast behavior and events in an evaluative mode and to suggest alternative modes of actions " (Zald, 1996: 262). Because agenda setting and advocacy involve both the provision of information and of normative frames, they crucially influence policy debates and outcomes (Sell and Prakash, 2004: 145). According to John Braithwaite and Peter Drahos (2000) “webs of dialogue” can be an important source of change in international politics. “Webs of dialogue” or “webs of persuasion” describe efforts in which actors seek to alter others’ interests. As they suggest, “issue definition is the first form of persuasion delivered by dialogic webs that is a prerequisite for a global regime”(Braithwaite and Drahos, 2000: 553). Indeed, in their survey of global business regulation, they conclude that webs of dialogue are much more frequent catalysts of change than are webs of coercion.

Global governance in intellectual property protection, as exemplified by the 1994 Agreement on Trade-Related Aspects of Intellectual Property (TRIPS hereafter) in the WTO, has come about by the mechanism of coercion (Abbott, 2002; Braithwaite and Drahos, 2000; Sell 1998; 2003). However, in the aftermath of TRIPS and the contest between those who frame intellectual property as a trade issue and those who frame it as a health issue webs of dialogue are becoming increasingly important. As Braithwaite and Drahos point out, “dialogic webs offer individuals the possibility of micro action to secure macro change” (2000: 7). Competing knowledge networks participate in dialogic webs in their efforts to define issues, persuade others to redefine their interests, and inject normative commitments that shape prescriptions, and seek to persuade others that “compliance is morally right” (Braithwaite and Drahos, 2000: 553). Authors working in the rational choice tradition focus on processes given preferences. As Patrick Jackson has pointed out, rationalist accounts are silent on the issue of legitimacy; “what vanishes from sight …are any notions of persuasion, learning, reflective reconsideration or any of the other activities that go on when a leader tries to render a policy acceptable to an audience” (2002: 744). Authors concerned with questions of legitimacy and negotiation processes focus on the *content* of actors’ beliefs and principled argument (Albin, 2001; Coleman and Gabler, 2002; Crawford, 2002; Keck and Sikkink, 1998; Mueller, 2001). I will argue that principled argument used in dialogic webs has the potential to alter actors’ interests and outcomes. While coercion is a viable weapon of the strong, principled argument can be a potent asset for the weak to bring about desired change -- especially when coupled with the strategic use of institutions.

The institutional dimension concerns the broad range of different multilateral institutions that are promulgating laws, declarations, resolutions, and soft law related to global public health. These institutions reflect competing conceptions of which values should be promoted. Since WTO law is binding and enforceable, it is imperative to examine its role and its relationship to other institutions to assess the prospects for and obstacles to global governance in public health. The institutional dimension is also addressed in a lively

debate among scholars of international law about the boundaries of the WTO and the extent to which declarations, laws, and regulations promulgated in other venues are relevant to WTO deliberations. It also addresses the question of what role the WTO should play in resolving politically-charged value conflicts. This issue is central to conflicts over intellectual property because a variety of different international organizations have weighed in on the matter, and these organizations reflect competing and conflicting conceptions of intellectual property. Competing values are at stake both outside of and within the WTO. For example, WTO judicial panels hearing cases involving pharmaceutical patent protection "face a major dilemma. [They] cannot simply recognize *a* public good in interpreting the TRIPS Agreement. [They] must rather take account of concerns over competing public goods as reflected in the agreement's provisions" (Shaffer, 2003a: 4-5). "The ultimate issue in choosing among the production of public goods becomes institutional because different institutions offer different opportunities for actors to participate, affecting which perspectives on the appropriate balancing are advanced" (Shaffer, 2003a: 5). This raises an urgent problem of which perspectives should have pride of place in interpretations of states' rights and obligations.

This paper begins by sketching out the broadest structural framework. It goes on to describe the issues at stake. The next section identifies the varieties of discourse and their purveyors. Then it maps out several of the key institutions relevant to trade, intellectual property and public health. It then offers conclusions and speculates on the possibilities for a way forward.

STRUCTURAL DIMENSIONS

A deep structural impetus to economic globalization and liberalization emerged from the increasing mobility of capital. Capital mobility and the ideological shift toward a radical free market agenda served to enhance the power of global corporations and particularly those engaged in knowledge-intensive processes and production. In effect, these structural and ideational factors delivered these corporations to the forefront of global business regulation. The growth of offshore capital markets, the removal of capital controls, financial deregulation, and the cross-border integration of capital markets has created "an explosion in the availability of private liquidity which governments are hard pressed to control" (Germain, 1997: 105). As a consequence, transnational corporations in knowledge-intensive sectors such as computers, software, and pharmaceuticals "have the resources, motivations and capabilities to roam the world searching for the kinds of opportunities that promise lucrative rewards" (Germain, 2000: 81). These corporations have become increasingly influential in policymaking in the United States because of their positive trade balances and their contribution to the state's competitiveness goals. Now, "the private interests of the market are integrated into the state, asymmetrically, and in accordance with their structural power and organizational capacity, through their close relationship to state institutions in the policy decision-making process" (Underhill, 2000: 129). These trends are central to the current discussion because these firms and their governments have rewritten the rules of international trade. Further, they have been

pushing high protectionist norms in intellectual property protection at every conceivable level.

In the name of "competitiveness" the United States relaxed its formerly stringent antitrust (competition) laws. Throughout the 1980s anti-trust law increasingly recognized that intellectual property rights do not *necessarily* "confer monopolies or even market power in any relevant market" (Webb and Locke, 1991: 2457 at note 29). The Reagan administration's concern over its industries' abilities to compete effectively in world markets resulted in a more permissive approach to merger control that reflected the Chicago School of economics (Eisner, 1991). The U.S. Justice Department argued that "anti-trust laws should not be applied in a way that hinders the renewed emphasis on competitiveness"(Hoff, 1986: 19). With regard to intellectual property, both the administrators and the courts have adopted the view that an intellectual property owner has no relevant market power (in terms of anti-trust) if close substitutes exist for the product or process. This more flexible approach, when coupled with newly broad definitions of what constitutes a relevant market, redounds to the benefit of the intellectual property owner in comparison to the pre-Chicago approach. The consequence of this new thinking was to remove most intellectual property licensing from anti-trust scrutiny. Under the Reagan administration,

> The executive agencies viewed the economic incentives provided by intellectual property rights as legitimate means of extracting the full economic benefit from innovation. Intellectual property rights acted as a 'magic trump card' allowing many previously suspect arrangements to proceed without challenge from the Federal Trade Commission or the Department of Justice (Hayslett, 1996: 382).

The 1980s has been referred to as an "anything goes era" for intellectual property licensing arrangements (Yurko, quoted in Hayslett, 1998: 382, note 33).

Furthermore, intellectual property rights have been dramatically expanded in recent years to cover things such as computer programs, compilations of data, genes, entire plant species, software algorithms, pharmaceutical products and processes, "practices in local agriculture, medicine and education which were outside of market relations" (Arup, 1998; see also Correa, 2002). This combination of relaxed anti-trust policies and expanded intellectual property rights has promoted economic concentration in high technology sectors, and particularly in the life sciences industries. This trend has been well documented by scholars and non-governmental organizations (Dutfield, 2003; Drahos with Braithwaite, 2003; Shulman, 1999; Genetic Action Resources International, 1998). The consequences include enhanced political power of these industries, the reduction in the number of suppliers of certain kinds of technology, the reduction of competition, and the higher costs of technology. As Omer suggests:

> Developing countries are confronted with the following dilemma: on the one side, in order to attract more investment and technology they have to press to open up their markets, and on the other side, the reduction of regulatory barriers gives rise to the emergence of anti-competitive behavior of firms (Omer, 2001: 322).

Even more ominously, Drahos (with Braithwaite) argues that:

> The globalization of intellectual property rights will do much to rob knowledge of its public good qualities. When knowledge becomes a private good to be traded in markets the demands of many, paradoxically, go unmet. Patent- based R&D is not responsive to demand, but the ability to pay…. Much of what happens in the agriculture and health sectors of developed and developing countries will end up depending on the bidding or charity of biogopolists as they make strategic commercial decisions on how to use their intellectual property rights (2003: 167-168).

So what does all this mean for public health? Structural features at the macro level shape the micro level, as manifest in the under-provision of drugs for tropical diseases, public health budgets reduced under IMF conditions, and the constrained ability of governments to meet public health needs. Furthermore, "the weakness of regulatory frameworks in [low and middle income countries] in the face of emerging global health markets leaves their populations especially vulnerable" (Buse et. al. in Lee et. al. eds 2002: 260).

The rise of private power in the context of globalization has also led to the "marked ascendance of private (for profit) sector actors in health policy in recent decades within the context of a 'global shift' in the world economy" (Buse et al in Lee et al 2002: 261). Economic concentration in the life sciences industries, coupled with the expanded property rights afforded by TRIPS, has translated "economic power into greater influence over policy-making that has hitherto been seen as the realm of the public sphere" (Buse et al, 2002: 261). Recent years have witnessed the proliferation of global private-public partnerships (GPPPS). "Health GPPPs are those collaborative relationships which transcend national boundaries and bring together at least three parties, among them a corporation (and/or industry association) and an intergovernmental organisation so as to achieve a shared health-creating goal on the basis of a mutually agreed and explicitly defined division of labour" (Buse and Walt, 2002: 44). Among the concerns raised by GPPPs include that of representative legitimacy; "it would appear that GPPPs provide the commercial sector with improved access to decision-making within the U.N., which is not balanced by special access to recipient countries and marginalised groups" (Buse and Walt, 2002: 60). An example of a GPPP is the Global Alliance for Vaccines and Immunizations (GAVI) launched by Bill Gates together with the executive heads of WHO, UNICEF, the World Bank and Merck & Co." (Buse and Walt, 2002: 51). In connection with the HIV/AIDS pandemic, industry has suggested "long-term donation programs instituted by pharmaceutical companies" (Buse and Walt, 2002: 54). GPPPs have been initiated to discourage the use of compulsory licensing to facilitate access to medicines. For example, "the Bristol-Myers Squib's partnership with UNAIDS and a variety of actors in southern Africa, 'Bridging the Gap', has been cited as the way forward in lieu of compulsory licensing" (Buse and Walt, 2002: 55). In response to these changes, developing countries and NGOs increasingly have mobilized to check this expansion of commercial power.

TRIPS and the Issues

The most important public international law covering intellectual property is the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) administered by the World Trade Organization (WTO). Unlike most international law, TRIPS is binding and enforceable. The WTO may authorize states to sanction those found to be in violation of the agreement. TRIPS reflects the interests of the owners of intellectual property. Indeed, its very existence and much of its substance owes much to just a handful of global firms based in the United States (Drahos with Braithwaite, 2003; Matthews, 2002; Sell, 2003). TRIPS extends patent rights for twenty years, requires developing countries to offer patent protection for pharmaceuticals, sharply circumscribes the conditions under which states may issue compulsory licenses, and reduces states' autonomy in crafting domestic intellectual property policies that suit their diverse levels of innovation and economic development. From the standpoint of economic development and technology transfer, TRIPS represents the most challenging public international law. In a sharply worded and bold critique, a United Nations Development Program (UNDP) report stated that "countries at low levels of human technological capability cannot benefit significantly from TRIPS. Developing countries are not likely to be even at least as well off under TRIPS as they would be outside it"(UNDP, 2003, quoted in McDowell).While some critics call for TRIPS' abolition, such as the UNDP report, others argue that it is workable for developing countries if interpreted appropriately (Reichman and Lange, 1998). Everyone agrees that the short-term consequences will be massive resource transfers from developing countries to owners of intellectual property. The World Bank has estimated that TRIPS should yield an annual $19 billion for the United States, whereas South Korea would sustain the largest loss - $15 billion (World Bank, 2001: 133).

Countries that consume and import intellectual property will pay a higher premium to those who produce and export it. Under TRIPS, countries have agreed that importation of a product constitutes "working" the patent. However, importation represents only a passive mode of technology transfer, and once again raises concerns that firms will use patents to maintain import monopolies. Those concerns had animated the earlier New International Economic Order (NIEO) approach to patents (Sell, 1998). Another consequence of TRIPS is that it offers "hardly any incentive for the patentee to license his technology. The technology holder can serve the large and small markets with his enhanced rights without licensing the technology"(Verma, 2001: 344).

Overall, TRIPS reflects and promotes the interests of global corporations that seek to extend their control over their intellectual property. These firms, acting through the U.S. government (and with the support of Europe and Japan), largely captured the WTO process and succeeded in making public international law to suit their particular needs. The battle over access to essential medicines revolves around the rights to issue compulsory licenses, and to manufacture and export generic versions of brand name drugs. Global brand name pharmaceutical corporations seek to restrict the ability of generic manufacturers to produce and distribute essential medicines. African countries in the grip of the HIV/AIDS pandemic, Brazil, India, and their NGO advocates seek to

clarify interpretations of TRIPS that permit compulsory licensing, parallel importing, generic manufacture and export.

DISCURSIVE DIMENSIONS

The debate over TRIPS and access to medicines has galvanized a broad range of stake-holders. Brand name pharmaceutical companies (a.k.a. global pharma), developed and developing country governments, the Office of the United States Trade Representative (USTR), NGOs representing public health and consumer interests, and generic drug manufacturers are all participating in this vigorous debate. Among the competing values embedded in TRIPS are the generation of knowledge, the facilitation of "undistorted" trade, and the protection of public health (Shaffer, 2003a, 1).

On one side of the TRIPS and access to medicines debate are those who support strong intellectual property protection for pharmaceuticals, and argue that, if anything, TRIPS is too weak. These advocates highlight the high costs of developing new drugs, the importance of strong property rights as incentives for innovation, and the need for substantial compensation for providing life saving drugs (Grabowski, 2002: 849-860). This view is most prominently associated with brand name global pharmaceutical industry, the United States, and the USTR. It has also been influential in the WTO. The industry fears that any expansion of cut-rate drugs will undermine their markets, particularly if they find their way into high income industrialized country markets. Global pharma highlights potential health dangers of widespread generic production, “piracy”, and the use of drugs without the supervision, dosing instructions, and regulatory controls covering global pharma’s products (Mallett and Finston, in Warner, 2002: 675-751).

Perhaps the most frequently offered argument from supporters of global pharma is that the big problem is not patents but poverty (Attaran in Warner, 2002: 675-751; Bate and Tren, 2003; Calfee, 2003; Mallett in Warner, 2002: 675-751). This view has been promulgated in industry-supported American think tanks such as the American Enterprise Institute and the International Intellectual Property Institute. Bate and Tren presented their remarks at an American Enterprise Institute forum on “unelected” NGOs (2003). The U.S.-based Pharmaceutical Research and Manufacturing Association (PhRMA), an industry lobbying group, is hardly subtle about its efforts to enlist academics to promote its cause. The Washington Post has referred to these as “hall-of-mirrors techniques by which special interests amplify their arguments through seemingly unconnected third parties” (2003). For example, in the coming fiscal year, PhRMA has budgeted $1 million for an:

> “intellectual echo chamber of economists – a standing network of economists and thought leaders to speak against federal price control regulations through articles and testimony.” It has set aside $550,000 “for placement of op-eds and articles by third parties” and at least $2 million for outside research and policy groups “to build intellectual capital and generate a higher volume of messages from credible sources” backing industry positions. Overall, the group will devote $12.3

> million to “alliance development”, … with economists, doctors, patients, and minority groups (Washington Post, 2003).

PhRMA frequently cites a “Harvard study” that “proves” that patents are no obstacle to access to antiretroviral medicines in Africa (Attaran and Gillespie-White, 2001). Attaran was an adjunct lecturer in public policy at Harvard, and his co-author worked for a PhRMA-supported think tank the International Intellectual Property Institute (Abbott, 2002: 485). The oft-cited paper originated as a study that PhRMA commissioned with its think tank (IIPI) headed by Bruce Lehman, former U.S. Commissioner of Patents (Abbott, 2002: 485 at note 62). The U.S. trade delegation relied on this then-unpublished study in its Talking Points in late September 2001 in the run up to the WTO Doha Ministerial meeting (Abbott, 2002: 485).

Substantively, advocates of PhRMA’s position object to any weakening of intellectual property protection through public health exceptions. They reject compulsory licensing as a policy tool to bring the costs of essential medicines down. They reject parallel importing (Finston and Mallett in Warner, 2002), whereby states can take advantage of differential pricing policies and import the cheapest version of the brand name pharmaceutical. Overall, they ardently oppose any efforts to weaken the international system of intellectual property protection. Instead, they advocate increased foreign aid, drug donations from firms, and “protection for international price discrimination against the threat of ‘grey market’ arbitrage” (Bloche, 2002:838).

On the other side of the debate is an alliance of developing country governments and NGOs campaigning for access to essential medicines. They argue that patent protection *is* a barrier to access and that public health exceptions to patent rules are necessary to prevent needless deaths. They advocate compulsory licensing, generic competition, and fixed rates of compensation for pharmaceutical companies.

Among the most outspoken advocates of this position are James Love of American consumer activist Ralph Nader’s Consumer Project on Technology (CPT), and Ellen ’t Hoen of Medecins Sans Frontieres (MSF). They consistently have attacked PhRMA’s positions on these issues. Ellen ’t Hoen points to strong intellectual property protection as one important barrier to access; she argues that patent protection leads to high prices and limited access (2002: 27). MSF and other NGOs have expressed a number of concerns about TRIPS including: high drug prices; reduced availability of quality generic alternatives; inadequate R&D into tropical diseases; and bilateral pressures on developing countries to adopt patent protection that exceeds the requirements of TRIPS (’t Hoen, 2002: 29-30). For example, only 13 of 1233 new drugs marketed between 1975 and 1997 were approved for tropical diseases. As Hammer suggests, “there is a substantial wedge between the public health needs of developing countries and what private drug markets are likely to deliver. As a result, the rhetoric of strong intellectual property rights leading to innovation that meets social needs rings particularly hollow in this setting” (2002: 888). Furthermore, Love has challenged PhRMA’s claims that its companies spend US$500-800 million developing each new drug. Love has argued that the majority of important HIV/AIDS drugs were actually developed by the public National Institutes of Health, and funded by taxpayers’ dollars (Consumer Project on Technology). Love and

others have also criticized the Attaran and Gillespie-White (2001) argument (Love, in Warner, 2002: 732-735; CPT et. al. 2001).

Brazil, India, and the African group of countries have been leaders in the intergovernmental efforts to address their public health emergencies. As Jose Viana, a Brazilian trade delegate, remarked, "the Brazilian government has consistently supported the idea that public health should not be subordinate to abuses of economic power" (2002: 311). Activists have praised Brazil's policies of providing universal access to HIV/AIDS drugs (Rosenberg, 2001). Brazil has used the threat of compulsory licensing to negotiate steep drug discounts with global pharma. It also has committed resources to producing generic drugs. Its policies have helped to create a market for high quality generic drugs (Love in Warner, 2002: 702). Creating a market has encouraged competition. As a recent WHO report concludes, "competition is perhaps the most powerful policy instrument to bring down drug prices for off-patent drugs" (Creese and Quick, 2001, quoted in Abbott, 2002: 472). Above all, the access to medicines campaign endorses the right of developing countries to compulsory license drugs, to produce and export generic drugs, and to take advantage of parallel importing to seek out the lowest cost medicines.

INSTITUTIONAL DIMENSIONS, THE WTO: SOCIAL ISSUES AND LEGAL DEBATES

Since the WTO administers TRIPS, the "hard law" that public health advocates have sought to clarify and interpret in flexible ways, the role of the WTO is important to examine in greater detail. Clearly, public health and trade have both social and economic dimensions. NGOs and developing countries have criticized the WTO as being insufficiently responsive to social needs. The question arises, to what extent should social policy be incorporated into the WTO? If so, how should it be incorporated? "While many accept the WTO essentially as currently constituted, others find it increasingly difficult to conceive of a multilateral trade regime confined exclusively to promoting economic efficiency through trade liberalization in isolation from other values" (Stein, 2001: 508). Alvarez argues that one's analysis of the WTO is dependent upon one's perspectives on the relevant stakeholders and the WTO's mandate. While some maintain that the WTO strictly exists to serve the "producers of goods", others see the WTO as charged with serving "marginalized developing countries, NGOs and individuals" (Alvarez, 2002b: 154). Indeed, the question is how to balance the interests of these stakeholders within a trade framework. Ultimately, the questions of linking public health, intellectual property, and trade are both normative and political.

We can approach these issues more systematically by considering two analytic dimensions: the reasons behind linking trade and social policy, and the mechanisms for doing so. Reasons for linking trade and public health could be: "(1) normative (because linkage is demanded by justice and fairness); (2) coherence (because a free trade regime would simply not make sense if [public health is] ignored; (3) consequentialist (because free trade will adversely affect [public health]; (4) strategic (because linking these issues

in a creative package leads to more effective negotiations as to both); or (5) effectiveness (because the more effective WTO approach to dispute settlement can be usefully 'borrowed' to the benefit of [public health])" (Alvarez, 2001: 12-14).

A second dimension is the mechanisms for linking these issues. At least three institutional alternatives exist within WTO for balancing competing policy goals. The first would be to interpret TRIPS flexibly in order to facilitate national solutions to balancing conflicting goals; the second would be to apply TRIPS stringently to establish a common floor that all nations would have to meet so as to limit national interpretive discretion; and the third would be for the judicial panel to engage in judicial activism on a case-by-case basis, taking account of the broader policy landscape (e.g., WHO, UNAIDS, UNCTAD) (Shaffer, 2003a: 10). The first route would give developing countries more scope to tailor the TRIPS provisions to their specific needs. The second would rest ultimate authority in the intergovernmental political bargain struck in achieving TRIPS. This approach would leave it up to states to negotiate trade-offs between public health and trade. The third route, frequently advocated by legal scholars pushing non-market agendas, would empower the WTO judicial panels to resolve value conflicts. Public health and trade could be linked interpretatively in a top down manner whereby the WTO's Appellate Body interprets the meaning of the relevant laws (interpretive linkage).

Advocates of a broader stakeholder approach for WTO such as Robert Howse argue that, "rather than attempt once again to decide what is 'in' or 'out of' the WTO, we should try to mold the rules and their interpretation to structure the *interaction* of the trading regime with other powers and authorities, both domestic and international, in a legitimate manner" (Howse, 2002: 112). In this perspective, legitimacy would be the yardstick by which to measure the process and outcomes. As Shaffer suggests, "scholars of different ideological orientations tend to identify their ideological goals with particular institutions and thus tend to idealize those institutions. Power tends to disappear within their preferred institutions" (2003b: 3). However, one must examine these institutions in their political context, and that invariably implicates power.

For example while the WTO judicial "interpretive" approach may seem appealing on the face of it, both Shaffer and Dunoff have made compelling arguments against it. First, as Shaffer points out, structural asymmetries militate against extensive developing country participation in WTO litigation (2003a: 14). For example, in many cases the costs of litigating a WTO claim, (US$300-400,000 in attorneys' fees), are prohibitive. "The 'haves' come out ahead in litigation at the international level where legal expertise is highly specialized and expensive" (Shaffer, 2003b: 11). Dunoff has argued that based on the GATT/WTO record, panels are more likely to decide cases in ways that militate against a non-market outcome (2001). This argument powerfully questions the assumption that judicial activism would tend in a "progressive" direction. Furthermore, "WTO judicial bodies decide ... cases in a highly-charged political context. They are not free from political pressure, even if they do not expressly take it into account. They have their own institutional interests at stake" (Shaffer, 2003b: 26). "The WTO Appellate Body operates not as an ideal neutral judge, but one that takes into account its own institutional interests and shapes decisions to encourage compliance and consensus"

(Shaffer, 2003b: 29; Smith 2003).

Analysis of the Shrimp/Turtle case pertains to the prospects of the WTO's representation of a broader range of stakeholders. While parallels between access to medicines and the Shrimp/Turtle case are inexact (Shaffer, personal e-mail communication on file with author), the Shrimp/Turtle case seems to serve as a Rorschach ink blot test in legal scholarship. Scholarly interpretations of the significance of the case are hardly unambiguous. Some scholars advocating a broader stakeholder approach to trade find hope in the case, whereas others are far more wary. The first group of analysts argues that Shrimp/Turtle provides an important precedent for enlarging WTO's scope beyond trade. The second group bemoans the Shrimp/Turtle case for stretching the WTO too far. The third group draws more pessimistic conclusions about the significance of the case for WTO judicial activism. I will discuss each group in turn.

Advocates for change and for expanding WTO's mandate conclude that the Appellate Body report in the Shrimp/Turtle Case, "abandoned the WTO's isolationism, that the WTO is a self-contained system, …by examining whether an endangered species was an exhaustible resource, by referring to international environmental law" (Gathii, 2001: 155). The Appellate Body referred to a "baseline in actual international environmental law that was contained in the Rio Declaration on Environment and Development" (Howse, 2002: 110). Howse cites the recent Beef Hormones and Asbestos cases as additional examples of the Appellate Body's use of "a variety of jurisprudential techniques" to address the balance of economic and social values (2002: 109). Gathii also notes that the Appellate Body endorsed Article 31 of the Vienna Convention on the Law of Treaties as an interpretive reference for the WTO in the Standards for Gasoline case. In his judgment, "such instructions come down to a 'recognition that the General Agreement is not to be read in clinical isolation from public international law' (Gathii, 2001: 156). Pauwelyn argues that "WTO rules are not the alpha and omega of all possible trade relations between states. Other more detailed or special rules of international law continue to be highly relevant" (Pauwelyn, 2001: 540).

These analysts advocate the fuller explicit incorporation of social issues into the WTO and tend to highlight normative and consequentialist arguments to support their position. Further, they advocate interpretive linkage by invoking WTO Appellate Body decisions in defense of their arguments and the possibilities for expanded linkage (Abbott, 2000; Bloche, 2002; Charnovitz, 2002; Gathii, 2001; Gathii, 2002; Howse, 2002; Howse and Mutua 2000; and Pauwelyn, 2001). Some authors argue that social policy is already deeply embedded in the WTO (Gathii, 2001). For example, Bloche argues that in the WTO system the protection of health has become "a *de facto* interpretive principle when disputes arise over members' treaty obligations" (Bloche, 2002: 825). According to Bloche, the Doha Declaration on TRIPS and Public Health "has interpretative weight under the Vienna Convention on the Law of Treaties as either a 'subsequent agreement between the parties regarding the interpretation of TRIPS or 'subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation'" (Bloche, 2002: 842). Gathii agrees, arguing that "what the Doha Declaration … does as a matter of law is not insignificant. It mandates reading the TRIPS

Agreement in light of its objectives and principles, thereby giving countries a legal basis in the Agreement itself to argue in favor of public policies" (2002: 305).

Others argue that the WTO should be restricted to trade, *period* (Bhagwati; Steger) and advocate an incrementalist, bottom-up approach. These analysts tend to highlight strategic reasons and advocate "negotiation linkage." This group also presents a narrower conception of the WTO's mandate (Steger, 2002). At the end of the day these analysts warn against the dangers of expanding the WTO's mandate in the absence of a prior *political* consensus among the member states (Alvarez, 2001; 2002a; 2002b; Bhagwati, 2002; Steger, 2002). They raise concerns about the WTO's resource constraints (Bhagwati, 2002: 132), and the dangers of a damaging backlash if the WTO gets too far ahead of its membership (Alvarez, 2001). Both Bhagwati and Steger are careful to define their sense of the WTO's ultimate purpose. For Bhagwati, it is to promote "non-coercive trade" as a "mutually beneficial phenomenon" (2002: 127). By this yardstick he believes that TRIPS has no place in the WTO. Steger defines the WTO as an institution dedicated to promoting freer trade via the norm of nondiscrimination (and *not* fairness) (2002: 139). Bhagwati, unlike the first group of commentators, sharply criticizes the Shrimp/Turtle decision for precisely the reasons that the other commentators praised it. As he states "it would be more prudent for it not to let earlier findings be replaced so drastically as in the shift from the Tuna/Dolphin to the Shrimp/Turtle decisions, which was doubtless influenced to some degree by the environmental lobbies of the North. Instead, such dramatic reversals or changes are better made in negotiations than in courts" (Bhagwati, 2002: 133-134).

Bhagwati fears the explicit introduction of non-market criteria as opening a "Pandora's box" (2002: 133) and favors a stricter compartmentalization of functions between various international organizations. He believes, for example, that labor standards should be addressed in the International Labor Organization, and not the WTO. Some see this as a potentially cynical position – to shunt sensitive issues off to venues in which "words don't matter", using less authoritative institutions as a safety valve to defuse controversy (Shaffer, 2001: 38; Helfer 2003: 51). Steger also favors compartmentalization out of acute resource constraints as much as principles. For example, Irwin has pointed out that the WTO has a staff of only five hundred (three hundred of whom are translators), and an annual budget of just US$77 million. By contrast the World Bank employs 6,000 people and has an annual budget of about US$8 billion, and even many NGOs have much bigger budgets than the WTO. The World Wildlife Fund's annual budget is US$360 million, and Greenpeace has a budget of about US$120 million (Irwin, 2002: 186). According to Steger, one must question "whether the global commitment to free trade is strong enough to sustain a significant expansion of WTO competence to the full scope of trade-related environmental, social, and sustainable development issues…. For both the 'nationalists' concerned about state sovereignty, and the liberals concerned about democracy, the answer may be to 'stop the integration' and allow other (less integrated) international agencies (e.g. the ILO and mechanisms established by environmental treaties) to deal with the other values" (Stein, 2001: 507).

These analysts trace the development of the GATT/WTO system as a "bottom up"

process (J. Jackson, 2002; Alvarez, 2001). As such, they recommend that its continued evolution rest on a political process of negotiation among member states. Ultimately these authors see the problems as essentially political, and therefore advocate political solutions. Insofar as the WTO is “a system of rules” the “normative problems of interpreting and applying those rules cannot be avoided” (Steger, 2002: 138). Steger takes direct aim at the analysts who champion the Appellate Body’s potential to expand WTO’s purview. As Steger states: “this challenge of redefining and clarifying the values and policy objectives that the international community believes should trump the value of freer trade is too big and too important to be left to the judicial branch of the WTO, even at its highest level, the Appellate Body” (2002: 144).

A third group of scholars endorses a broader mandate for WTO, that it conform to a stakeholder model (Trebilcock and Howse, 2001: 54), but disagrees on mechanisms. As Dunoff states, "debates within and about the WTO tend to be consequentialist. that is, they tend to argue over what results will follow from adopting this or that rule, and whether such outcomes are desirable. In this context, the 'desirable' outcome is typically understood to be the outcome that maximizes economic welfare. But it is surely a mistake to understand the new trade issues exclusively in consequentialist terms" (Dunoff, 2001: 1008). Indeed, the new trade issues (such as intellectual property) are distributional and are not about "expanding the pie" (Dunoff, 2001: 1008). While Dunoff and Shaffer subscribe to the broad stakeholder view, they part company with Howse and Gathii insofar as they are leery about a "top-down" Appellate Body incorporation mechanism.

Scholars emphasizing the deeply political universe of the WTO draw different conclusions from the Shrimp/Turtle case (Smith, 2003; Dunoff, 2001). For instance, Dunoff argues that the Shrimp/Turtle case presents an ambiguous picture for champions of incorporation of "trade and" in the WTO. While heralded as a major step forward insofar as the Appellate Body held that "dispute resolution Panels and the AB itself have legal authority to receive amicus briefs and other materials from NGOs" (Dunoff 2001, 984-985), in fact the Appellate Body "proceeded to largely ignore the NGO arguments and instead 'focus' solely on the arguments the United States presented in its 'main submission'" (Dunoff, 2001, 985). Surveying additional cases, Dunoff concludes that WTO trends are a step backwards for advocates of greater NGO involvement in WTO deliberations. Rather than representing the infusion of independent ideas into the deliberative process, NGO submissions are routinely ignored unless adopted by one of the parties to the dispute. In essence, this has had the effect of diluting the possibilities of NGO input. "While doctrinal developments deprive NGOs of a powerful rhetorical argument about the closed nature of WTO dispute resolution, the actual procedure used effectively excludes NGOs from WTO dispute resolution" (Dunoff, 2001: 987).

INSTITUTIONAL DIMENSIONS:
Public International Legal Regimes, Institutions, Hard and Soft Law: WIPO, CBD, UNHCHR, WHO

The WTO is arguably the most important institution governing global intellectual

property policy. However, TRIPS is not the only important public international legal regime covering global intellectual property and WTO is not the only significant venue. WIPO, the Convention on Biological Diversity (CBD), the United Nations High Commissioner for Human Rights (UNHCHR), and the WHO are all actively engaged in making public international law in intellectual property. The following section seeks to map out the broader institutional terrain, focusing on WIPO, CBD, UNHCHR, and WHO. I will devote most of the discussion to WHO, due to its centrality to the medicines debate. As Stein points out, “any effort to rank IGOs in a hierarchical way is fraught with difficulties” (2001: 495). However, it is important to highlight each organization’s perspective on the issue before discussing the relationships between them.

This discussion of the institutional dimensions of global public policy making requires exploring reasons for shifting from one forum to another, available options, the choice of institutions, and the role of the WTO. According to Helfer, there are four main reasons why actors strategically choose to shift forums: "to help achieve desired policy outcomes; to relieve political pressure for lawmaking in other international venues; to generate counter-regime norms; and to integrate those norms into the WTO and WIPO" (Helfer, 2003: 48). These reasons are not mutually exclusive. Of these four reasons only the second of these, the "safety valve" strategy, is pursued in order to preserve the status quo. "States and interest groups can use regime shifting as a safety valve, consigning an issue area to a venue where consequential outcomes and meaningful rule development are unlikely to occur" (Helfer, 2003: 51; also see Shaffer, 2001: 38). The other three are pursued in order to affect change.

Governments, private actors, and NGOs all engage in forum shifting. Forum shifting can be done horizontally, across institutions, as in the case in which the U.S. pushed to move intellectual property policymaking from WIPO to GATT for the Uruguay Round (Sell, 1998). Forum shifting can also involve vertical moves, across levels of governance, such as the United States' use of Super 301 of the U.S. trade laws to coerce developing countries into adopting higher standards of intellectual property protection, or its more recent efforts to use bilateral and regional intellectual property and investment treaties to secure "TRIPS-Plus" protection in developing countries (Drahos, 2001). Actors may also choose among different institutions favoring those that afford them better access, or those which philosophies resonate more closely with their own goals. For example, actors can select a forum in which previously marginalized issues get a better reception. This can provide them with opportunities to propose and experiment with policy approaches to the issues (Helfer, 2003: 49). Forum shifting can provide governments that are critical of TRIPS a "safe space" in which to exchange information, develop soft law, and craft viable policy alternatives that address their concerns (Helfer, 2003: 52). Such soft law forums as the WHO and the CBD have proven to be significant incubators of alternative approaches, or "counter-regime norms", to TRIPS. As Helfer suggests:

> embedded in the very idea of counter-regime norms is a more strategic understanding of legal inconsistencies, one in which states consciously create conflicts as a way to subvert the prevailing legal landscape and provide fuel for renegotiating principles, norms, and rules to more accurately reflect their

> interests. ... Developing countries and NGOs used precisely this strategic approach in seeking to integrate the new rules developed in biodiversity,... public health, and human rights regimes into the WTO and WIPO.... [Such forum shifting] can function as an intermediate strategy that allows developing countries to generate the political groundwork necessary for a new round of intellectual property lawmaking in the WTO and WIPO. When adopting this 'integrationist' strategy, developing countries can use regime shifting to shore up support from hesitant allies, vet competing reform proposals, and generate common negotiating positions which they then introduce into the two organizations (2003: 53-54).

This strategy can also support the development of competing discourses that can change the way parties read TRIPS and are willing to apply it (Shaffer, personal e-mail communication on file with author). Furthermore, these competing discourses can challenge various domestic political bargains and integrate a broader range of viewpoints and parties into the issues. They can raise the political costs of defending the status quo (Sell and Prakash, 2004). With this in mind, the following discussion surveys TRIPS-related activity in diverse forums.

The NIEO negotiations on the revision of the Paris Convention for the Protection of Industrial Property took place in WIPO, which administered the Paris Convention. In the mid-1980s, in the waning days of those stalled negotiations, dissatisfied American negotiators shifted intellectual property deliberations out of WIPO and into the General Agreement on Trade and Tariffs (GATT). Americans, seeking high protectionist norms for intellectual property, favored GATT because it would permit them to link intellectual property protection to trade. The U.S. negotiators anticipated better results owing to the large and attractive U.S. market that could be used as negotiating leverage (Sell, 1998). The forum shifting of the mid-1980s was a major blow to WIPO's morale and prestige. However, it has bounced back with renewed energy. Since then, WIPO has substantially transformed itself from a relatively sleepy, albeit highly competent, organization into a more entrepreneurial agency with a mission to prove its continued relevance to intellectual property owners.

Unlike many international organizations, WIPO is almost self-sufficient. Rather than relying upon government handouts and grants, WIPO earns nearly 90% of its operating budget from its administration of the Patent Cooperation Treaty (PCT) (Doern, 1999; Drahos with Braithwaite, 2003: 111; WIPO, 2001). The biggest users of the PCT are the global corporations engaged in producing knowledge-intensive products and processes, such as the global life sciences industries and the financial services industries. These corporations also are the most ardent champions of high protectionist norms for intellectual property. These budgetary facts behind WIPO undoubtedly compromise its image as a technocratic, objective civil servant.

WIPO actively provides technical assistance to developing countries as they seek to comply with TRIPS. Those who pay WIPO's freight undoubtedly shape its advocacy, and it has urged a number of developing countries to adopt "TRIPS-Plus" provisions in their national legislation. For example, WIPO assisted in formulating the revised Bangui

Agreement for the Organisation Africane de la Propriete Intellectuelle (OAPI) countries. This agreement goes further than TRIPS by placing greater restrictions on the issuance of compulsory licenses and prohibiting parallel imports (Commission on Intellectual Property Rights, 2002: 156). Indeed, in the wake of TRIPS, "the United States regularly sent lawyers for the U.S. pharmaceutical and copyright industries to Geneva as 'faculty' of WIPO to teach developing country representatives about intellectual property matters and draft 'model' laws for their consideration. Industry successfully lobbied Congress to allocate funds for these 'educational' efforts" (Shaffer, 2003a: 7).

WIPO is also conducting negotiations on a Substantive Patent Law Treaty that aims for harmonization of patent law globally. After a failed effort that ended in 1991, new talks began in 2001 and many suspect that the momentum behind the renewed effort is animated by a quest to increase property rights protection beyond that embodied in TRIPS. The 1991 effort produced a draft that largely was a hybrid of U.S. and European laws. This prompted one developing country delegate to point out that "there was a paradox that through a harmonisation process, the majority of countries were being asked to align their law with the provisions of a minority" (Commission on Intellectual Property Rights, 2002: 132). The current deliberations pose a danger to developing countries insofar as they could universalize TRIPS-Plus standards. Furthermore, it is important to avoid "one-size-fits-all" approaches to intellectual property protection.

But developing countries have also seized opportunities to press their agendas, more fully developed in other venues, within WIPO. They sought to link biodiversity issues to the 1999 WIPO Patent Law Treaty negotiations by proposing the incorporation of the CBD recommendation that intellectual property applicants, when using genetic resources, prove that they had obtained informed prior consent to access those resources (Helfer, 2003: 62). In response, WIPO agreed to establish a separate body within WIPO to address intellectual property aspects of resources and traditional knowledge. Subsequently, the Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore (IGC hereafter) has conducted a number of studies that reflect the developing countries' concerns as expressed in the Convention on Biological Diversity (CBD)'s Conference of the Parties (COP). While to this point the IGC's activities have "emphasized soft law studies and reports", governments are debating public health, biodiversity, plant genetic resources, and traditional knowledge issues "in the hard law negotiations over the SPLT" (Helfer, 2003: 64). Developing countries have also requested that the WIPO Secretariat examine the implications of the SPLT for the IGC's work, that "illustrates their increasing recognition of the need to coordinate lawmaking not only across different regimes or venues, ... but also in different fora within the same intergovernmental organization" (Helfer, 2003: 64).

The CBD is yet another international law that includes intellectual property elements. Unlike TRIPS and the WIPO efforts, it more explicitly and squarely incorporates provisions that developing countries favor. The CBD recognizes the rights of indigenous cultures to preserve their knowledge resources; Article 8j recognizes communal knowledge. The CBD conception challenges the TRIPS view that endorses the western, individualistic conception of knowledge ownership; this western perspective draws a

sharp line between “folklore” and “science.” CBD stresses that biological resources are sovereign resources of states whereas TRIPS enforces private property rights over them. Many developing countries and NGOs endorse CBD as a way of combating “biopiracy” in which global life sciences corporations expropriate genetic resources and traditional knowledge without authorization or compensation. W.R. Grace’s patenting of the neem tree seed extracts became a lightning rod for this controversy. Furthermore, CBD also offers more opportunities for upholding farmers’ rights against “biogopolists.” Article 8j calls for respect and preservation for “innovations … and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity.” India has called for the primacy of CBD over TRIPS 27.3(b) (the provision requiring members to provide protection for plant varieties either by patents or an effective *sui generis* system).

The CBD's COP, the CBD member states that decide how to apply and implement the CBD, has addressed the degree of compatibility of the CBD with TRIPS. "After the entry into force of TRIPs, developing states led by China and the G77 and sympathetic NGOs such as the World Wildlife Fund began to express concern over the relationship between intellectual property rights and the CBD's access and benefit sharing rules" (Helfer, 2003, 29). The COP convened a panel of experts that led to the adoption of the Bonn Guidelines in 2002, which stipulated that applicants for intellectual property rights should disclose the origin of any genetic resources or related knowledge relevant to the subject matter. Such disclosures are meant to facilitate monitoring whether applicants have received prior informed consent of the country of origin and complied with the country's conditions of access (Helfer, 2003: 29). While CBD's COP states have urged cooperation with WTO and WIPO, they have:

> pointedly refrained from ceding jurisdiction over biodiversity-related intellectual property issues to these organizations and instead are attempting to influence the terms of the debate by setting agendas, convening meetings, suggesting topics for further study, proposing a memorandum of understanding with WIPO, and directing the CBD's Executive Secretary to seek observer status with the TRIPS Council (Helfer, 2003: 30).

The WTO Ministerial Declaration of November 2001 instructed the TRIPS Council to examine the relationship between the TRIPS Agreement and the CBD; this is an important development insofar as it constitutes a frank recognition of conflicts that will need to be addressed (Abbott, 2002: 489). It also demonstrates the migration of an issue developed in CBD into the WTO; the developing countries' proposals were derived from the Bonn Guidelines (Helfer, 2003: 60-62).

Human rights organizations increasingly have devoted their attention to intellectual property issues. Under a human rights rubric, intellectual property is recast as “a social product with a social function and not primarily as an economic relationship” (Chapman, 2002: 867). The organizations adopt resolutions, declarations, and reports that are not legally binding. "In July 2000, an NGO consortium composed of the Lutheran World Federation, Habitat International Coalition, and the International NGO Committee on

Human Rights in Trade and Investment submitted a statement to the Chair of the Sub-Commission" on the Promotion and Protection of Human Rights (Helfer, 2003: 44). The statement underscored fundamental conflicts between TRIPS and human rights. In November 2000 the UN Committee on Economic, Social, and Cultural Rights held a day long session on intellectual property rights that led to the adoption of a statement in November 2001 endorsing a normative framework for intellectual property rights. The UN High Commissioner's report on the impact of TRIPS on human rights addressed the medicines issue (UN High Commissioner, 2001). This report endorsed the public health and developing country activists' position on TRIPS, and highlighted the high cost of patented drugs as a barrier to health. It also discussed Brazil's program as a positive model for expanding access to medicines. In this venue, NGOS, independent experts, and developing countries have framed the TRIPS rules as "a threat to economic, social, and cultural rights" and have displayed an antagonistic approach to TRIPS (Helfer, 2003: 41). The Sub-Commission on the Promotion and Protection of Human Rights has criticized the WTO quite sharply, stating in one draft report that "the WTO is a 'veritable nightmare' for certain sectors of humanity and criticize[d] WTO rules as 'grossly unfair'" (Dunoff, 2001: 998). The WTO Secretariat responded by criticizing the report's methodology, language and conclusions claiming that they were unsubstantiated by the evidence. The Secretariat suggested "a meeting with WTO officials to correct the 'significant misunderstandings' included in the report" (Dunoff, 2001: 999). The Sub-Commission ... has requested that the High Commissioner for Human Rights seek observer status with the WTO for the ongoing review of TRIPS (Chapman, 2002: 880).

Patrick Wojahn points out that the right to health is guaranteed under numerous conventions including Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), Article 25 of the Universal Declaration of Human Rights, and Article 11 of the Convention on the Elimination of All Forms of Discrimination Against Women (2001/2002: 466). Even though the United States has not ratified the ICESCR, Wojahn argues that the right to health should be considered to be "customary international law" because 143 states are parties to the Covenant and the right to health is included in numerous other treaties (2001/2002: 496). The UN human rights bodies have focused considerable attention on intellectual property issues, spanning public health, technology transfer, agriculture, indigenous peoples, and cultural dimensions of human rights. These bodies would like to see human rights concerns prevail over intellectual property rights. Many of the human rights approaches to health have been developed from the WHO (Wojahn, 2001/2002: 469).

The WHO is a specialized agency of the United Nations system. Its mandate is to direct and coordinate authority for health work (Stein, 2001: 497). WHO has the largest budget of all the specialized agencies, with an annual budget of "$1.8 billion dollars contributed by its member states" (Volansky, 2002: 229). WHO increasingly has been drawn into trade issues since TRIPS, and NGOs have had considerable access to the institution. In 1999 "the WHO granted official status to nearly two hundred NGOs" (Stein, 2001: 498). Even though global pharma has an important voice in WTO through its powerful OECD member states that contribute significant funding, WHO has been criticized for its "failure to cooperate with the private sector" (Stein, 2001: 498). The director-general, secretariat, and health expert staff significantly shape agendas and outcomes.

The WHO has been active in the access to essential medicines campaign (Sell, 2002: 504-506). Governments and NGOs first deliberated in the WHO over the very issues that led to the Doha Declaration on TRIPS and Public Health. In 1996 public health activists and developing country member states, including Brazil, South Africa, and Zimbabwe, expressed concerns about access to medicines in connection with globalization and TRIPS. The World Health Assembly adopted a resolution on a Revised Drug Strategy that asked the WHO to examine the impact of the WTO on national drug policies and essential drugs, and to make recommendations for collaboration between the WTO and WHO. "This resolution gave the WHO the mandate to publish, in 1998, the first guide with recommendations to Member States for implementing TRIPS while limiting the negative effects of higher levels of patent protection on drug availability" ('t Hoen, 2002: 36). The WHO Essential Drugs Policy concentrates on the supply and use of about 250 drugs that are considered to be most essential and important for public sector provision.

In 1998, Zimbabwe's Minister of Health asked Bas van der Heide of the NGO Health Action International (HAI) to produce a draft resolution for a "Revised Drug Strategy." The Revised Drug Strategy is a document designed to assist developing countries in their health planning and policy implementation. The proposed document drew from work that HAI had been doing with consumer activist Ralph Nader's group Consumer Project on Technology (CPT) headed by James Love. Van der Heide and Love had crafted language for the Free Trade of the Americas negotiations advocating compulsory licensing, parallel importing, and stressing the priority of health concerns over commercial interests. "A small technical group within the WHO began to prepare and distribute concrete recommendations for coping with TRIPS by using the built-in flexibility to ameliorate the effects of introducing its requirements. These recommendations included … authorizing parallel importation and granting compulsory licenses where appropriate" (Abbott, 2002: 474-475). This incensed the brand name global pharmaceutical industry because the document endorsed the very practices that this sector was fighting through the United States Trade Representative. "The U.S. and some European countries unsuccessfully pressured the WHO in an attempt to prevent publication of the guide" ('t Hoen, 2002: 36). Commercial pharmaceutical interests felt that WHO's involvement in this issue presented a threat to a trade-based approach. The United States has resisted WHO's efforts to help developing countries gain access to medicines, but the EC has shifted its views in recent years and has become more supportive of WHO's role in this area (Helfer, 2003: 39).

In May 1999 WHO's World Health Assembly unanimously enacted resolution WHA 52.19 (World Health Assembly, 1999) calling upon member states to ensure equitable access to essential drugs and review options under international agreements to safeguard access to these medicines. The WHO continues to pursue strategies designed to increase developing countries' access to essential drugs. As Abbott points out:

> A number of training seminars regarding TRIPS implementation have been conducted with public health, patent office, and trade officials. These activities of WHO remain relatively unpublicized because increased attention would risk

> drawing a stronger reaction from Pharma. However, it is becoming substantially more difficult to find developing country officials who are unaware of compulsory licensing, parallel importation, and the importance of patent application reviews" (2002: 475).

In 2001 the WHO adopted two resolutions that addressed the need to strengthen policies to increase access to medicines, and the need to evaluate the impact of TRIPS ('t Hoen, 2002: 36). It also published a bulletin highlighting WHO's policy guidelines and urging developing countries to refrain from implementing TRIPS-Plus intellectual property provisions (WHO, 2001; Helfer, 2003: 39-40).

In the spring of 2001, the Zimbabwean Ambassador Boniface Chidyausiku requested a special TRIPS Council session on access to medicines. The session was held in June. The Quaker United Nations Office in Geneva provided support for developing country delegates and a number of legal scholars, economists and activists provided technical support (Sell, 2002: 512). As expressed by the Brazilian delegate, the meetings were intended to "eliminate the imprecision in international agreements concerning public health. In matters involving public health, developing countries want WTO judges to interpret the TRIPS Agreement in a manner that benefits public health" (Viana, 2002: 314). The TRIPS Council resolved to continue analyzing the degree of flexibility afforded by TRIPS and planned future meetings on the issue. Momentum to address the issue accelerated throughout the summer and fall. The U.S. withdrew a WTO intellectual property case against Brazil, the UN General Assembly held a special session devoted to the HIV/AIDS pandemic, and Secretary-General Kofi Annan announced the establishment of a Global Fund to Fight AIDS, Tuberculosis, and Malaria (Sell, 2002: 513). In September 2001 the TRIPS Council met again to discuss the access to medicines issue. The African group presented a draft text for a ministerial declaration on TRIPS and public health emphasizing that "nothing in the TRIPS Agreement shall prevent Members from taking measures to protect public health" ('t Hoen, 2002: 41).

In the September preparations for the upcoming WTO Doha Ministerial meeting, some participants discussed the possibility of WHO/WTO collaboration in preparing a guide to assist developing countries in implementing TRIPS while protecting public health. An accidentally leaked memo provided a WTO critique of WHO's role (Abbott, 2002: 475 at note 26). An e-mail message from the Director of Intellectual Property for the WTO, Adrian Otten, was mistakenly included in a submission to the TRIPS Council by Australia and then recalled. The message states:

> To be frank I have my doubts about the wisdom and feasibility of attempting a joint guide with WHO and this still remains to be seen…. I do feel very strongly, for reasons indicated below, that we should not send it to WHO prior to Doha…. I have two major concerns on the TRIPS side. The first and most important is that I think it unnecessarily risky for the WTO Secretariat to share texts on the TRIPS Agreement's provisions on pharmaceuticals with the WHO at this stage…. It is important to recognize that there is a network which includes the leading non-governmental people, certain people in the WHO Secretariat, …and many

> developing country delegates and nothing that is given to WHO can be relied upon to remain confidential…. My second concern about TRIPS is that it does not, as yet, contain a section which discusses the positive impact of the TRIPS Agreement on public health, namely through promoting research and development into new drugs…. The main messages that we would want to give are: (a) that open trade and a movement towards more open trade brings with it higher standards of health; and (b) concerns that the WTO rules will stand in the way of legitimate health measures are unfounded" (IP-Health, Otten, Sept. 21, 2001: 1-2).

Not only does the message reveal a somewhat tense relationship between the two organizations, it also clearly incorporates the PhRMA perspective as revealed in Otten's "second concern." Indeed, PhRMA executives have boasted about their close relationship with and extensive access to the WTO Secretariat (Basu, 2003:7; Forbes, 2003).

In the run up to Doha, human rights activists supported WHO's approach to the medicines issue (Chapman, 2002: 879) and participated in the access to medicines lobbying process. More dramatically, in the wake of anthrax attacks in the U.S. in September 2001, the U.S. and Canada announced plans to compulsory license ciprofloxacin (Cipro). Ultimately these governments negotiated steep price reductions with Bayer, just as Brazil has done with Roche and others. The irony that the U.S. was suddenly prepared to do precisely what it had complained about to the WTO was lost on no one. Numerous commentators have noted the political importance of this event in the successful conclusion of the Doha meeting (Abbott, 2002: 486-488; Sell, 2002: 515-516; 't Hoen, 2002: 42; Vieira, 2002: 320).

In November 2001, WTO members unanimously endorsed the Doha Declaration of TRIPS and Public Health. While not, by its terms, legally binding, it largely embraced the WHO and NGO view that TRIPS should not be a barrier to developing countries seeking access to medicines. This opens the possibility that the norms expressed in the Doha Declaration become legally binding either through a dispute resolution report that so holds, or otherwise (Dunoff, personal communication on file with author). Reactions to the Declaration predictably have been mixed with PhRMA interpreting it as an endorsement of intellectual property rights, many NGOS and developing countries seeing it as an important victory, and scholars debating what it really means (e.g., Charnovitz, 2002; Garcia-Castrillon, 2002; Horlick, 2002; Schott, 2002; 't Hoen, 2002: 43-44; Wolff, 2002). The Declaration postponed the politically contentious issue of the ability of generic manufacturers to export drugs to countries without manufacturing capacity. This was deferred to the so-called Paragraph 6 negotiations at the TRIPS Council. The WTO deadline for resolving that issue came and went in December 2002. The U.S., reflecting the wishes of its brand name pharmaceutical corporations, stood alone and used its veto to block the interpretation that 140 other countries have supported (Elliott and Denny, 2002). Meanwhile, the WHO busily tried to craft constructive approaches to this issue.

A May 2003 WHO report endorsed the NGO/developing country approaches to the medicines issue (WHO, 2003a). The report emphasized the neglect of tropical diseases,

the Doha Declaration's recognition that pharmaceutical products require special treatment, and the negative effects of patent protection on drug pricing. Further, the report recommended expanded competition as the most effective way to reduce drug prices. The report also took a critical view of "TRIPS-plus" provisions as being detrimental to health care. The director-elect of the WHO, Jong Wook Lee, announced measures that will make Brazil AIDS policy the foundation for the WHO efforts in this area. He asked the Brazilian Health Minister to release Paulo Teixeira, head of the administration's AIDS program, "to formulate the new policy for combating AIDS throughout the world, based on Brazil's experience" (BBC, 2003). This represents important recognition of Brazil's leadership role, and support for the developing countries' and NGO positions.

The May 2003 World Health Assembly meeting on improving access to essential medicines was particularly volatile. The U.S. presented a resolution that neglected even to mention the Doha Declaration, and did little more than assert the value of strong intellectual property protection as a stimulus for innovation (Lancet, 2003). The U.S. proposal further requested the WHO to refer Member States to the WTO and WIPO for assistance in implementing TRIPS obligations (Third World Network, 2003). Brazil proposed a resolution, supported by Bolivia, Ecuador, Indonesia, Peru, Venezuela, and South Africa on behalf of the members of the WHO African Region. The Brazilian proposal reflected developing country concerns about access to medicines, and called for an independent commission to examine the relationship between intellectual property rights, innovation, public goods, and public health. The developing countries sought an international committee much like the UK Commission on Intellectual Property Rights (CIPR, 2002), that was critical of overly strong patent rights as a barrier to access. When it was clear that no one supported the U.S. resolution, the Brazilian, Americans and several African delegations worked out a compromise that a WHO committee adopted by consensus. The resolution called for the establishment of a time-limited independent commission, whose terms of reference have yet to be drafted and it omitted any reference to "TRIPS-plus" obligations in bilateral and regional trade agreements. NGOs bemoaned the fact that the developing countries' proposals had been watered down in the compromise. However, the Doha Declaration is prominently featured in the resolution, and Member States were urged to arrive at a solution to the Paragraph 6 Doha Declaration impasse prior to the Cancun WTO Ministerial in September 2003 (World Health Organization, 2003b).

A TRIPS Council meeting held June 4-6, 2003 ended in a deadlock over the Paragraph 6 issue. Harvey Bale, president of the Geneva-based International Federation of Pharmaceutical Manufacturers Associations, stated that there had been no progress since the talks collapsed in December 2002. He referred to the December 16th draft text as "a license to steal" and claimed that "all research-based companies have problems with December 16" (Waddington, 2003). However, just before the Cancun Ministerial in September 2003 the United States finally relented in its adamant opposition to developing countries' proposals for a Paragraph 6 solution. Developing countries threatened to hold the Round hostage in the absence of a Paragraph 6 agreement. WTO members adopted an interpretive decision that "allows developing countries that lack sufficient domestic

manufacturing capacity to meet their public health needs by importing generic drugs from other WTO members without restriction as to type of disease or type of emergency" (Helfer, 2003: 60; WTO, 2003). The WTO General Council issued a decision implementing paragraph 6 of the Doha Declaration that "waived obligations set forth in paragraphs (f) and (h) of article 31 of the TRIPS Agreement so as to facilitate the grant of 'compulsory licenses' for the supply of medicines from any third country to countries with insufficient manufacturing capacities in the pharmaceutical sector" (Shaffer, 2003a: 8).

Clearly international organizations involved in intellectual property issues are divided over the merits of diverse multilateral approaches to intellectual property protection. The WTO and WIPO seem to champion the interests of property holders over property users (or producers over consumers), whereas the CBD, the Human Rights organizations, and WHO promote approaches that at the very least seek to balance the rights of producers and consumers. These divisions provide opportunities for developing countries and NGOs to change the agenda by re-framing issues in ways that enlarge their scope of action. For example, linking intellectual property to environmental protection as in the CBD, or to public health as in the WHO can build effective challenges to the more narrow trade-based conception enshrined in the WTO or the economic efficiency notions reflected in WIPO. Redefining intellectual property from being a trade issue to a public health issue resulted in the Doha Declaration. This has opened up an important space for debate on the costs and benefits of intellectual property protection as enshrined in TRIPS.

CONCLUSION AND THE WAY FORWARD

The foregoing has important implications for the access to medicines campaign and the quest for global governance of public health more generally. The access to medicines campaign, in particular, has provided several important lessons. Re-framing issues can be an effective way of creating space for debate and reconsideration of the conventional wisdom. By recasting intellectual property as a public health issue, policymakers are increasingly forced to confront the unconscionable trade-off between economic gain and unnecessary death. This has raised the political costs for those seeking to defend the status quo. "In a world of asymmetric power, developing countries enhance the prospects of their success if other U.S. and European constituencies offset the pharmaceutical industry's pressure on U.S. and European trade authorities to aggressively advance industry interests" (Shaffer, 2003a: 20). When brought to light through public action and media attention, the use of economic coercion to reduce access to medicines can become "politically unpalatable for U.S. and EC government and corporate elites" (Shaffer, 2003a: 21; Sell and Prakash, 2004). By mobilizing to reduce domestic political support for the status quo in the most economically powerful and influential countries, "developing countries retain greater leeway to develop intellectual property policies to fit their own needs" (Shaffer, 2003a: 20). They will need considerable support to enable them to resist pressures to adopt pernicious TRIPS-Plus provisions in bilateral and regional agreements. Highlighting the unintended and devastating consequences of particular policies can be a powerful rhetorical strategy. The HIV/AIDS pandemic underscored just how costly overly strong patent protection can be. The anthrax/bio-terror

threat in the United States led American policymakers to threaten compulsory licensing of Bayer's ciprofloxacine to ensure adequate supplies. The access to medicines campaign capitalized on this hypocrisy and it softened the American stance at Doha. Additionally the SARS epidemic of spring 2003 led to an expansion of the WHO's mandate, and a further empowerment of NGOs within the public health context. In May 2003 the WHO assembly approved changes to international health regulations to strengthen WHO's ability "to respond to global public health threats based on information from non-governmental sources" (Financial Times, 2003).

Even without obvious economic power the African block, Brazil, India and their NGO advocates have begun to make inroads on global intellectual property policy by strategically shifting forums and advancing new arguments. For instance, the CBD recasts intellectual property as both an environmental issue and a potential obstacle to sustainable agriculture. Environmental preservation, and the ability of states to feed their own people are powerful values that can lead people to question the primacy of economic efficiency as the sole yardstick by which to measure policy effectiveness. While the WTO and WIPO seem to represent both the economically and politically most powerful, the work of the WHO and CBD can have an impact on the work of these other agencies. The Doha Declaration on TRIPS and Public Health is a good example of that. Recasting intellectual property as a human rights issue could be an effective strategy to the extent that intellectual property rights are implicated in battles over the rights to food and medicines. No single "re-framing" will open up the dialogue and change global policies, but cumulative concerted efforts from a variety of angles could serve to weaken the consensus that backed TRIPS and lead to a more balanced approach to intellectual property rights.

Soft and hard law developed in non-WTO venues via developing countries' strategic forum shifting has enhanced their bargaining power within the WTO and WIPO. Developing countries and their NGO supporters deliberately promoted issue migration, on health from the WHO to the WTO, and on human rights and indigenous people to WIPO. Strategic forum shifting:

> facilitated a proactive negotiating strategy, enabling governments and NGOs to coordinate their efforts around hard and soft law proposals first vetted and refined in other international venues. This integrationist approach also allowed states to justify their demands for reform by invoking rules and principles endorsed by officials of intergovernmental organizations and by legal and technical experts. Support from these seemingly neutral actors gave the demands the imprimatur of legitimacy. And it allowed proponents to frame their arguments as rational efforts to harmonize potentially inconsistent treaty obligations and soft law standards that many states had agreed to, rather than as self-interested attempts to distort trade rules or to free ride on foreign creators or inventors. Seen from this perspective, even the soft law intellectual property standards generated in the biodiversity ... public health, and human rights regimes had hard-edged consequences. They acted as progenitors of proposals to revise legally binding rules within the WTO and WIPO (Helfer, 2003: 55-56).

Returning to issues raised at the outset it is important to bear in mind the relationships between international institutions. Given the fact that the WTO embodies hard law, it exists in somewhat of a hierarchical relationship compared to its soft law counterparts. Beyond the hard/soft law distinction, the WTO has cooperated more extensively with those international institutions (IMF and World Bank) that share its basic pro-market philosophy (Dunoff, 2001: 999). Indeed, the WTO also has expressed some overt antagonism toward both the WHO and the UNHCHR. Nonetheless, since much of the debate over TRIPS interpretations will be discursive (Shaffer, 2003a: 20) "soft law will be an important tool for WTO panels to use in resolving ... arguments [over competing objectives]" (Helfer, 2003: 69). While the deliberate generation of counter-regime norms in alternative forums has many benefits, it also risks the injection of further uncertainty and incoherence into efforts at global governance of public health (Helfer, 2003: 75). Without authoritative guidelines for resolving such issues, it may facilitate outcomes that favor the structurally powerful at the expense of others.

In order to reduce some of the power asymmetries, it would be helpful to institutionalize expertise and technical support for developing country delegations in Geneva. Peter Drahos has suggested the establishment of a “counter Quad” for developing countries that would function somewhat like the Cairns groups of agricultural exporters (Drahos, 2003: 96). The idea is to provide continuity and technical support on diverse issues to help to balance information and expertise asymmetries between the resource abundant delegations and most of those from developing countries. This expertise would need to be provided by developing country representatives and experts eager to protect developing countries’ interests. Support provided by the Quaker United Nations Office in Geneva during the negotiations over the Doha Declaration on TRIPS and Public Health is a good example of this latter type of assistance. UNCTAD, in conjunction with ICSTD, also has assembled a panel of intellectual property experts that have helped to craft reports and documents to assist developing country negotiators negotiate intellectual property issues.

At the national level, developing countries should pursue vigorous competition legislation. Competition law can provide an important check on abuses of intellectual property rights. Even though the Reagan administration gutted American anti-trust practice with respect to intellectual property rights in the name of competitiveness, consumer groups and developing countries can lobby for competition policies that check the abuses of the new “global knowledge cartels”(Drahos with Braithwaite, 2003: 206). Indeed, for most of the 20th century American anti-trust laws kept patent power in check (Sell, 2003). Competition policies can facilitate healthy markets and keep costs down. Technical assistance directed to this end would be invaluable.

While the structural picture poses daunting obstacles to the access campaign, the personal, emotional, and subjective nature of health may give the subject added punch. As Bloche argues, the infiltration of health issues into the WTO through the SPS Agreement and the Doha Declaration:

> rests on the intensely subjective, highly variable nature of people's beliefs about health danger. We appreciate and respond to health risks in ways shaped much less by statistical magnitudes than by the feelings that these risks evoke and our sense of control over these risks…. And public decision-making mechanisms that fail to offer opportunities for community control, or at least engagement, tend to raise people's anxieties about the risk-benefit judgements reached. …. National, let alone transnational, efforts to systematize and rationalize health policies encounter skepticism and resistance. Pushed too far, these efforts undermine the credibility, indeed the perceived legitimacy, of governments, and public, multinational institutions (Bloche, 2002: 845).

This paper has just begun to chart out the relationships between competing knowledge networks, international institutions, and normative concerns in the quest for global governance in public health. An important issue for further research is specifying the conditions under which principled arguments and persuasion help the weak to achieve important goals. Neta Crawford (2002), William Coleman and Melissa Gabler (2002) have done important work in this vein, and offer excellent ways to begin to address this vital question. Combining this set of concerns with negotiation analysis could be a fruitful way to proceed (Albin, 2001; Mueller 2001). Additionally, further examination of relationships between intergovernmental institutions is imperative. It matters a great deal whether they see themselves as in horizontal or hierarchical relation to one another. Analysts should continue to explore the intersection of knowledge networks, governments, multilateral institutions, international law, global business regulation, and social policy.

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