GAUGING THE POWER OF GLOBAL CIVIL SOCIETY: Intellectual property and public health

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ABSTRACT

For the past decade the activists and non-governmental organizations that form global civil society (GCS) have waged a sustained campaign to force the great powers to allow public health "flexibilities" in the enforcement of Trade-Related Intellectual Property (TRIPS). GCS advocates have claimed notable successes, culminating in the 2001 Doha Declaration on the TRIPS Agreement and Public Health. This apparent success challenges mainstream IR approaches to studying the global political economy. This paper critically examines the GCS narrative on TRIPS and public health, and finds two flaws: a neglect of alternative explanations for the policy change, and an overestimation of the magnitude of the policy shift. Global civil society did play a role in shifting policy on intellectual property rights – but the role has been exaggerated both before and after the Doha declaration.

Introduction

Ever since the 1994 Agreement on Trade-Related Intellectual Property (TRIPS) came into force, NGOs, public health advocates, and transnational social movements have argued that the agreement severely restricts access to life-saving drugs in the developing world. In the late nineties, these elements of global civil society (GCS) banded together to push for less stringent IPR enforcement for most countries in the world. Soon afterward, both the United States and European Union began softening their stance on the strict enforcement of TRIPS. In November 2001, at the Doha Ministerial meeting of the World Trade Organization (WTO), member governments addressed this concern by signing off on the "Declaration on the TRIPS Agreement and Public Health" or Doha declaration. This declaration stated that:

[T]he TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.¹

The Doha declaration went on to delineate the various conditions under which countries could use the "flexibilities" of TRIPS to address public health problems. In August 2003, an additional WTO agreement was reached to clarify remaining ambiguities from the Doha declaration.² These events were the culmination of a sustained campaign by global civil society designed to scale back intellectual property restrictions on the production and distribution of generic drugs to the developing world. A developing country delegate

¹ "Declaration on the TRIPS Agreement and Public Health," http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

² "Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health". 30 August 2003. Accessed at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm, 11 August 2005.

told one researcher, "what negotiators like me failed to accomplish Oxfam and MSF [Médecins Sans Frontières] have accomplished"³

Mainstream paradigms of international relations would appear to have a tough time accounting for the shift in global governance emanating from the Doha Declaration. Ordinarily, when the two largest trading powers (the US and EU) and powerful economic sectors embedded in those economies (pharmaceutical companies) embrace the status quo, there is little chance that global civil society should be able to alter the outcome. And yet, this appears to be exactly what happened If true, this example would rebut arguments made by neorealists,⁴ neoliberals,⁵ and even some constructivists⁶ about the primacy of the state in determining global governance outcomes. Such an outcome would also present powerful evidence from a "least-likely case" for scholars working in the GCS paradigm.⁷ According to these scholars, global civil society was responsible for both the Doha Declaration and similar events.⁸

This paper takes a critical look at the case to see if GCS arguments hold up to closer empirical scrutiny. The data suggests that global civil society did have some causal effect on great power foreign policies and the changes to the TRIPS regime with regard to public health. This influence, however, has been overstated in several ways. As with other prominent cases, the GCS narrative omits alternative explanatory variables and exaggerates the extent of the policy shift. National security considerations also help to explain the change in intellectual property rights (IPR) policy towards a more flexible view of TRIPS. Furthermore, the preferences of the great powers strongly conditioned the final extent of the shift. The great powers conceded more than they would have preferred at Doha, but this was due to transient factors unrelated to the GCS campaign. After the Doha Declaration, the United States and European Union acted to ensure that the carve-out for public health fit with their (slightly altered) preferences rather than

³ Quoted in Peter Drahos, "Developing Countries and International Intellectual Property Standard-Setting," *Journal of World Intellectual Property* 5 (May 2002)

⁴ Kenneth Waltz, *Theory of International Politics* (New York: McGraw-Hill, 1979); Robert Gilpin, *Global Political Economy* (Princeton: Princeton University Press, 2001).

⁵ Andrew Moravcsik, *The Choice for Europe: Social Purpose and State Power from Messina to Maastricht* (Ithaca: Cornell University Press, 1998).

⁶ Alexander Wendt, *Social Theory of International Politics* (Cambridge: Cambridge University Press, 1999).

⁷ Harry Eckstein, "Case Studies in Political Science," in Fred Greenstein and Nelson Polsby, eds., *Handbook of Political Science*, volume seven (Reading, MA: Addison-Wesley, 1975), p. 118.

⁸ Aseem Prakash and Susan Sell "Using Ideas Strategically: The Contest Between Business and NGO Networks in Intellectual Property Rights," *International Studies Quarterly* 48 (Spring 2004): 143-175; Drahos, "Developing Countries and International Intellectual Property Standard-Setting."

those of global civil society. As time has passed, great power governments have appropriated the normative frame of improving public health to advance their own policy aims. There is little evidence that the United States government in particular has fundamentally altered its preferences on the issue. In other words, the power of GCS norms to alter state interests appears to exist, but the magnitude of the effect is limited.

This paper is divided into six parts. The next section briefly outlines the basic tenets of the global civil society paradigm. The third section offers a theoretical and empirical critique of these arguments, with a special emphasis on cases highlighted by GCS scholars. This critique serves as a useful guide for examining possible flaws in the treatment of the TRIPS case. The fourth section discusses the GCS narrative on the public health exception to TRIPS; the fifth section critically examines this narrative to determine the causal mechanisms behind the outcome. The final section summarizes and concludes.

The global civil society paradigm⁹

The past decade has witnessed an outpouring of research into the role that non-state actors play in affecting global governance outcomes. What is taking place today in the debates about the role of non-state actors echoes similar debates from three decades ago. During the early 1970's the global economy seemed to be buffeted by one shock after another. This triggered a surge of research into the ways in which complex transnational interdependence could alter the behavior of states.¹⁰ This research emphasized the ways in which non-state actors and the global economy constrained states.

Like the work of the early seventies, the current literature on global civil society is heterogeneous in its details but shares some common themes. The most important thread that runs through the literature is that it is comprised of non-state actors that transcend individual nation-states. As Ronnie Lipschultz notes: "While the participants

⁹ Significant portions of the next two sections come from Daniel W. Drezner, *Who Rules? The Regulation of Globalization*, book manuscript, University of Chicago, IL, June 2005.

¹⁰ See, for example, Robert Keohane and Joseph Nye, *Transnational Relations and World Politics* (Cambridge: Harvard University Press, 1973); Keohane and Nye, *Power and Interdependence* (Boston: Scott Foresman, 1978),

in the networks of global civil society interact with states and governments over particular policy issues, the networks themselves extend beyond levels of analysis and state borders, and are not constrained by the state system itself."¹¹ The growth of global civil society makes these non-state actors too powerful for states to ignore.¹² Ann Florini and P.J. Simmons assert that, "Transnational civil society is a piece – an increasingly important piece – of the larger problem of global governance."¹³ Some writers go further, arguing that these groups are now powerful enough to bypass the state entirely, leading to a "world civic politics."¹⁴

Most of these scholars argue that the multiple components of global civil society are organized as a network characterized by voluntary, reciprocal and horizontal patterns of communication and exchange of information.¹⁵ Different nodes of a network must be able to exchange information for this type of organization to be effective. The power of networked actors has been long established in the social sciences. The denser the network, the more effective non-state actors can be. One trigger of globalization has been the persistent decline in costs of transportation and communication. The development of the Internet, e-mail and cellular phones, combined with the deregulation of air travel, enhances the networking power of global civil society.¹⁶

GCS actors affect outcomes by establishing and strengthening global norms. As Martha Finnemore and Kathryn Sikkink observe, the spread of norms across governments is a time-consuming, three-stage process of emergence, socialization, and internalization.¹⁷ If a sufficient number of actors embrace an emergent norm, a cascade effect will ensure wide proliferation and internalization to the point that even great

¹¹ Ronnie Lipschutz, "Reconstructing World Politics: The Emergence of a Global Civil Society." *Millennium* 21 (Spring 1992), p. 393.

¹² Keck and Sikkink, *Activists Beyond Borders* (Ithaca: Cornell University Press, 1998); Peter J. Spiro, "New Global Communities: Nongovernmental Organizations in International Decision-Making Institutions." *The Washington Quarterly* 18 (Winter 1994): 45-56; Robert O'Brien, Anne Marie Goetz, Jan Aart Scholte, and Marc Williams, *Contesting Global Governance* (Cambridge: Cambridge University Press, 2000).

¹³ Ann M. Florini and P.J. Simmons, "What the World Needs Now?" in Ann Florini, ed., *The Third Force: The Rise of Transnational Civil Society* (Washington: Carnegie Endowment for International Peace, 2000), p. 3.

¹⁴ Paul Wapner, "Politics Beyond the State: Environmental Activism and World Civic Politics," *World Politics* 47 (April 1995): 311-340.

¹⁵ Keck and Sikkink, Activists Beyond Borders, p. 8.

¹⁶ Ronald Deibert, "International Plug 'n Play? Citizen Activism, the Internet, and Global Public Policy." *International Studies Perspectives* 1 (July 2000): 255-272.

¹⁷ Martha Finnemore and Kathryn Sikkink, "International Norm Dynamics and Political Change," in Peter Katzenstein, Robert Keohane, and Stephen Krasner, eds., *Exploration and Contestation in the Study of World Politics* (Cambridge: MIT Press, 1999).

powers cannot resist them. These norms are designed to clarify situations of uncertainty or ignorance to both elites and masses. Some GCS actors help to implement norms by "naming and shaming" actors that violate their principled beliefs. This activity raises the political costs of contravening those normative regimes, leading to a recalculation of preference orderings by self-interested actors. As the dynamic density of GCS actors increases, so does their effect on outcomes. Margaret Keck and Kathryn Sikkink point out: "Networks operate best when they are dense, with many actors, strong connections among groups in the network, and reliable information flows." Keck and Sikkink also hypothesize that issues involving "bodily harm to vulnerable individuals" or "legal equality of opportunity" will inspire the most concerted GCS campaigns. This implies that GCS actors should have enhanced influence over public health policies.

The trouble with the GCS paradigm

Many of the flaws in the GCS approach echo the problems with the first wave of research on transnational actors three decades ago.²⁰ Michael Clarke noted that the first wave of transnationalism research, "certainly does not constitute a theory; it is rather a term which recognizes a phenomenon, or perhaps a trend in world politics, a phenomenon from which other concepts flow."²¹ While the current wave of GCS scholarship is more theoretically rigorous, a critical review of GCS scholarship reveals two methodological flaws. First, by focusing on description rather than causation, the empirical work conflates GCS activity with affecting outcomes. This can lead to cases that suffer from the qualitative equivalent of omitted variable bias – a failure to examine alternative explanations for the outcome. Second, even in cases where GCS activity is deemed to be pivotal, the magnitude of policy shifts are often exaggerated.

GCS research has focused more on descriptive inference than causal inference.²² Sidney Tarrow concludes, "Analysts in this burgeoning field have been better at

²⁰ On the similarities between the GCS literature and Keohane and Nye's work in the seventies, see Alejandro Colás, *International Civil Society* (Oxford: Polity Press, 2002), chapter one.

¹⁸ Keck and Sikkink, Activists Beyond Borders, p. 28.

¹⁹ Ibid., p. 27

²¹ Michael Clarke, "Transnationalism," in Steve Smith ed., *International Relations: British and American Perspectives* (Oxford: Basil Blackwell, 1985), p. 146.

²² On the distinction, see King, Keohane and Verba, *Designing Social Inquiry*, chapters 2-3.

describing activities than at conceptualizing them in clear analytical terms."²³ Description is appropriate to a certain extent, since an emphasis of the school is on the constitution of non-state actors and the constitution of global norms. However, the empirical confusion between the visibility of global civil society and their precise role in affecting the aforementioned cases highlights the need for causal inference. Without specifying under what conditions GCS actors will succeed in altering global governance outcomes, there is an unfortunate tendency to assume causality for any event in which GCS activity was prominent.

This assumption – and the lack of rigorous process tracing that comes with it – threatens to crowd out equally compelling alternative explanations. As Alexander George and Andrew Bennett recently observed, "Too often, researchers focus great attention on the process-tracing evidence that interests them most, while giving processtracing evidence that bears on alternative explanations little attention or using it only to explain variance that is not adequately explained by the hypothesis of interest."²⁴ The empirical literature on global civil society confirms this problem. Scholars working in the GCS tradition have primarily tested their arguments by looking at specific episodes of peak GCS activity. Therefore, most of the case studies take the form of "easy tests." 25 However, even looking at these cases, there is reason to question the explanatory power of the GCS approach.

For example, Peter Haas argues that an epistemic community, based in the United Nations Environmental Program, elite research institutes, and national governments, was responsible for persuading governments to agree to cooperate on the Montreal Protocol on stratospheric ozone.²⁶ In particular, Haas focuses on the epistemic community's ability to use a scientific hypothesis to develop a norm against further ozone depletion. According to his account, this network was able to persuade an ideologically hostile Reagan administration, as well as the DuPont corporation, of the connection between chlorofluorocarbons (CFCs) and the ozone layer. The GCS approach uses a similar

²³ Tarrow, "Transnational Politics," p. 10. See also Florini and Simmons, "What the World Needs Now?"

²⁴ Alexander George and Andrew Bennett, Case Studies and Theory Development in the Social Sciences (Cambridge: MIT Press, 2005), p. 217. This problem can be particularly acute with GCS literature, because scholars working in this tradition often identify with the normative aims of the civil society groups they are analyzing.

²⁵ One exception is the land mine case, which is discussed below.

²⁶ Peter Haas, "Banning Chlorofluorocarbons: Epistemic Community Efforts to Protect Stratospheric Ozone." International Organization 46 (Spring 1992): 187-224.

narrative to explain the international whaling regime and the 1992 Rio biodiversity summit.²⁷

There remain significant criticisms of this narrative, however. Lawrence Susskind argues that in general, epistemic communities rarely play a role in environmental governance: "a review of most of the international treaties negotiated since the 1972 Stockholm conference shows that scientific evidence has played a surprisingly small role in issue definition, fact-finding, bargaining, and regime strengthening." ²⁸

The Montreal Protocol would appear to be an exception to Susskind's assessment. Officials from the United Nations and the United States have acknowledged the importance of the scientific consensus in setting the agenda for negotiations. However, other parts of the narrative contradict the GCS approach. Mostafa Tolba, one of the key UN Environmental Program officials involved in the negotiations, says that the protocol would not have been completed if key states had not been able to bargain with each other *outside* the formal negotiation process – and hence away from non-state actors. This type of "green room" negotiation is antithetical to the principles underlying the GCS approach, which stresses the inclusion of non-state actors in decision-making procedures. Haas also overestimates the role that norms had to play in DuPont's decision to back successively tighter restrictions on CFCs. Kenneth Oye and James Maxwell note that DuPont had a substantial economic incentive to be the market leader in environmentally safe CFC substitutes.

As for more recent environmental negotiations, the GCS approach is correct about the visibility of transnational environmental networks. It is equally clear, however, that the success in implementing these accords is a function of the material interests of governments. For example, the uneven pattern of success in deforestation prevention has

²⁷ M.J. Peterson, "Whalers, Cetologists, Environmentalists, and the international management on whaling," *International Organization* 46 (Spring 1992): 147-186. More generally, see Wapner, "Politics Beyond the State," and Ann Marie Clark, Elizabeth Friedman, and Kathryn Hochstetler, "The Sovereign Limits of Global Society," *World Politics* 51 (Winter 1998): 1-35.

²⁸ Lawrence Susskind, *Environmental Diplomacy: Negotiating More Effective Global Agreements* (Oxford: Oxford University Press, 1994), p. 64; quoted in Michael Zürn, "The Rise of International Environmental Politics," *World Politics* 50 (Fall 1998): 617-649.

²⁹ Richard Benedick, *Ozone Diplomacy; New Directions in Safeguarding the Planet* (Cambridge: Harvard University Press, 1991). Mostafa Tolba, *Global Environmental Diplomacy* (Cambridge: MIT Press, 1998).

³⁰ Tolba, Global Environmental Diplomacy, p. 85.

³¹ See Kenneth Oye and James Maxwell, "Self-Interest and Environmental Management," in Robert Keohane and Elinor Ostrom, eds., *Local Commons and Global Interdependence* (London: SAGE, 1995).

little to do with the strength of transnational activist networks. As Keck and Sikkink acknowledge, the success in preventing deforestation correlates directly with the extent of World Bank leverage over recipient countries.³²

The haphazard and incomplete progress in preventing global warming is also inconsistent with the GCS approach. The strength of GCS actors and their network density was unquestionably higher for global warming than for ozone depletion.³³ One would expect a corresponding effect on the outcome. Instead, the U.S. withdrew from the Kyoto protocol, objecting to the unfair distribution of costs and the lack of enforcement measures.³⁴ Australia followed suit soon afterwards.³⁵ In July 2005 the United States launched the Asian Pacific Partnership for Clean Development and Climate with Australia, China, India, Japan, and South Korea. Australian Prime Minister John Howard observed that, "The fairness and effectiveness of this proposal will be superior to the Kyoto protocol."³⁶ While most of the participating states stressed that this new arrangement would not conflict with Kyoto, this move decreases the likelihood of unified global governance for greenhouse gases – despite sustained GCS activity.

Another issue for which global civil society was perceived as influential was investment. Scholars argue that transnational activist networks played a crucial role in the failure of the Multilateral Agreement on Investment (MAI), an OECD initiative launched in 1995 that would have standardized how governments could regulate foreign direct investment. A broad array of groups opposed the MAI, and took active steps to sabotage the negotiations. Drafts of the treaty were posted on web sites. Activists, representing 600 organizations from approximately 70 countries, dogged the negotiators at the OECD headquarters in Paris. In 1998, they also protested the agreement at meetings of the WTO and UNCTAD.

By October 1998 the MAI had stalled out; in December of that year the OECD announced that the negotiations would end without an agreement. European officials

³² Keck and Sikkink, Activists Beyond Borders, chapter four.

³³ Young Ho Kim, "The Conditions of Effective NGO Policy Advocacy: An Analysis of Two International Environmental Treaties." Presented at the International Studies Association annual meeting, New Orleans, LA, March 2002.

³⁴ Scott Barrett, "The Political Economy of the Kyoto Protocol," *Oxford Reviews of Economic Policy* 14, No. 4 (1998): 20-39; John Heilprin, "Bush Advisers Say Withdrawal from Climate Treaty Aids Economy," *Boston Globe*, 12 July 2002.

³⁵ Jason Koutsoukis, "Climate Deal with US Unveiled," Australian Financial Review, 1 March 2002.

³⁶ Quoted in Richard Lloyd Parry, "We Will Find A Cleaner Way, say World's Big Polluters," *London Times*, 29 July 2005.

acknowledged that the visibility of the protestors elevated the MAI negotiations from civil servants to the ministerial level. Stephen Kobrin concludes: "The story of the MAI is a cautionary tale about the impact of an electronically networked global civil society."³⁷ Other GCS scholars share this assessment.³⁸

While there is clear evidence that global civil society mobilized to halt the MAI, there is minimal evidence that they were the cause of the MAI's downfall. Because of a host of economic disputes, the member states were far from reaching an agreement. The U.S. and other OECD members had clashed over whether the extraterritorial sanctioning of foreign firms contained in the Helms-Burton Act violated the stated aims of the MAI. Non-EU members also opposed a blanket "carve-out" of the most-favored nation principle for the European Union. France and Canada wanted to protect their cultural industries from the agreement. The United States, as the largest exporter of popular culture, naturally opposed this. These disagreements were not close to being settled at the May 1997 deadline the OECD originally set. Granted a one-year extension, the final draft still contained almost 50 pages of country-specific exemptions.³⁹ When France pulled out of the negotiations, Prime Minister Lionel Jospin singled out the dispute over cultural protections as the primary motivation.

French officials also acknowledged civil society opposition as a factor in the breakdown of negotiations.⁴⁰ However, by the time GCS opposition was clearly expressed – the middle of 1998 – the negotiations were already in trouble. For the United States government, the first hint of GCS opposition came in February 1998, when a group of NGOs sent a protest letter – to the wrong government agency. Edward M. Graham concludes: "the negotiations were indeed in very deep difficulty before the metaphorical torpedo was fired by the NGOs… this torpedo thus was more a coup de grâce than a fatal blow in its own right."⁴¹

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³⁷ Stephen Kobrin, "The MAI and the Clash of Globalizations," *Foreign Policy* 112 (Fall 1998), p. 98. See also Deibert, "International Plug 'n Play?"

³⁸ Craig Warkentin and Karen Mingst, "International Institutions, the State, and Global Civil Society in the Age of the World Wide Web," *Global Governance* 6 (June 2000); Florini and Simmons, "What the World Needs Now?" p. 10.

³⁹ See Edward M. Graham, *Fighting the Wrong Enemy: Antiglobal Activists and Multinational Enterprises* (Washington, DC: Institute for International Economics, 2000), chapters 1-2.

⁴⁰ Government of France, "Rapport sur l'Accord Multilateral sur l'invetissement (AMI)," September 1998. http://www.finances.gouv.fr/pole_ecofin/international/ami0998/ami0998.htm, accessed 18 July 2002.

⁴¹ Graham, Fighting the Wrong Enemy, p. 16 and p. 40.

These cases indicate that GCS actors did affect international negotiations. However, the importance of that role is less clear. The cases also reveal a tendency for GCS scholars to conflate visible activity with influence. Other narratives of these episodes suggest that the activities of non-state actors was purely epiphenomenal. Because much of the GCS work tends to ignore competing explanations for outcomes, their case selection suffers. In choosing cases with overdetermined outcomes, the GCS school makes it difficult to evaluate the explanatory power of their approach.

This does not mean that GCS actors are necessarily irrelevant. There are clearly cases – such as the land mine treaty – where the participation of transnational activist networks was a necessary and sufficient condition for the eventual outcome.⁴² However, the land mine treaty highlights a different problem with the GCS approach – the tendency to overstate the significance of the policy outcome.

The 1997 Ottawa Convention banning the use of anti-personnel land mines was hailed as an exemplar case of GCS influence on a security issue. The Convention had the quickest negotiation and ratification phases of any security treaty. Kenneth Rutherford concludes that, "NGOs initiated the landmine ban by placing the issue on the international political agenda resulting in intense media and public attention.... NGOs helped articulate and codify the landmines issue into international law by changing how governments perceived the legality of landmines and the effects of landmine use." Richard Price concurs, noting that, "Members of humanitarian organizations were the catalysts for politicizing the issue of AP [anti-personnel] land mines; by teaching through networks they gained political converts and were instrumental in AP land mines being characterized as a crisis issue on the international agenda." His process-tracing of the case demonstrates that influence, which has led to 152 treaty signatories, including former land mine producers such as Great Britain and France.

While the GCS paradigm provides some explanatory power over this event, the magnitude of the policy shift in the outcome is debatable. The overwhelming majority of the signatories neither used nor produced land mines; their decision to embrace the treaty

⁴² Richard Price, "Reversing the Gun Sights: Transnational Civil Society Targets Land Mines." *International Organization* 52 (Summer 1998): 613-644.

⁴³ Kenneth R. Rutherford, "The Evolving Arms Control Agenda: Implications of the Role of NGOs in Banning Antipersonnel Landmines," *World Politics* 53 (October 2000), p. 76; Price, "Reversing the Gun Sights," p. 639.

is an example of coincidence of interests rather than genuine policy coordination.⁴⁴ One powerful piece of evidence that supports this argument is the virtual absence of monitoring, inspection, and enforcement provisions within the treaty itself.⁴⁵ Indeed. Rutherford points out that GCS activists *supported* the absence of enforcement mechanisms – because more stringent measures would have reduced the number of signatories.46

Emily Meierding suggests that for most countries, the Ottawa Convention was a low cost, low benefit issue.⁴⁷ Compliance with GCS demands was the easiest option available. For the military great powers, however, and states that relied on land mines for security, the costs of compliance were far greater. This is why China, Egypt, India, Iran, Korea, Pakistan, Russia, and the United States have no plans to ratify the treaty. Indeed, Price acknowledges, "to date states containing well over half the world's population have resisted taking meaningful unilateral measures or joining the Ottawa process."48 At a minimum, the empirical examples discussed in this section suggest that greater scrutiny is warranted for cited examples of global civil society influencing international interactions.

It would be wrong to say that global civil society had no effect in the cases discussed in this section. There is, however, reason to doubt the significance of GCS influence in these events. The relevant case studies either omit or downplay alternative explanations; changes in the dependent variable are overplayed. As George and Bennett have pointed out, "the reader-critic must consider whether the case analyst has 'imposed' a favored theory as the explanation. Have alternative theories that might provide an explanation been overlooked or inadequately considered?"⁴⁹

Getting to the Doha Declaration: the GCS narrative

⁴⁴ On this distinction, see Robert Keohane, After Hegemony (Princeton: Princeton University Press, 1984), and Jack Goldsmith and Eric Posner, The Limits of International Law (New York: Oxford University Press, 2005).

⁴⁵ 1997 Ottawa Convention, Articles 7-9, available at http://www.un.org/Depts/mine/UNDocs/ban-trty.htm (accessed 1 August 2005).

⁴⁶ Rutherford, "The Evolving Arms Control Process," p. 109-110.
⁴⁷ Emily Meierding, "Transnational Advocates and the International Regulatory Process," presented at the University of Chicago's Program on International Political Economy and Security, Chicago, IL, May 2005. ⁴⁸ Price, Reversing the Gun Sights," p. 640.

⁴⁹ George and Bennett, Case Studies and Theory Development in the Social Sciences, p. 105.

The TRIPS regime was designed to deal with the protection of all forms of intellectual property – patents, trademarks, and copyrights. As the prime mover behind the creation of TRIPS, it was not surprising that the United States immediately began to make aggressive use of the TRIPS provision to crack down on IPR violations in the developing world.⁵⁰ In the first five years of the WTO's existence, the United States filed more TRIPS cases than any other country.⁵¹

A majority of these filings were triggered at the behest of the Pharmaceuticals Research and Manufacturers of America (PhRMA), the principal lobbying organization for the pharmaceuticals sector. The motivations behind these TRIPS cases were varied – however, one obvious source of contention was the issue of antiretroviral (ARV) drugs that combat the HIV virus. By the nineties, the AIDS crisis in Africa had became acute – to the point where many countries in the region were suffering from absolute decreases in life expectancy.⁵² By the late nineties, approximately 8,000 people per day died of AIDS in the developing world.⁵³

The spread and cost of the disease prompted governments to search for ways to widen access to life-saving drugs. One attractive policy option was compulsory licensing – allowing local pharmaceutical firms to manufacture low-cost generic versions of ARVs without the permission of the patent holder. For countries lacking a domestic generic producer, another option was parallel importation – allowing the product made by the patent owner to be imported into the country without the patent owner's permission. This creates differential prices for the same drug in the same market.

PhRMA, representing the patent holders for ARVs, had a vested interest in the status quo of strict enforcement of the TRIPS accord. The economics of pharmaceutical production consist of massive fixed costs and very small marginal costs once a drug has been developed. Patents permit the inventor to hold an artificial monopoly on the product, allowing the firm to recoup its fixed costs. Without a strong IPR regime, the pharmaceutical sector feared it would begin to see its profits diminish. PhRMA further worried that any exception made to TRIPS would trigger a general erosion of intellectual

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⁵⁰ Susan Sell, *Power and Ideas: North-South Politics of Intellectual Property And Antitrust* (Albany: SUNY Press, 1998); Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* (Cambridge: Cambridge University Press, 2003).

⁵¹ Sell, *Private Power, Public Law*, p. 129;

⁵² United Nations Development Program, *Human Development Report 2004*, p. 143-146.

⁵³ Ellen 't Hoen, "TRIPS, Pharmaceutical Patents, and Access to Essential Medicines," *Chicago Journal of International Law* 3 (Spring 2002), p. 27.

property rights. For example, if the practice of parallel importation spread to the developed countries, the monetary losses from an inflow of generic ARVs would be considerable. Drug company representatives told South African president Thabo Mbeki that their problem with his government's moves towards the compulsory licensing of AIDS drugs was that, "what South Africa does is a precedent for other developing countries." Thailand's government received a similar message from the United States government when that country contemplated compulsory licensing. 55

To change the status quo, a group of AIDS activists and public health advocates formed the Access Campaign to lobby the governments and IGOs that the TRIPS accord should not interfere with the production and exchange of generic ARVs. Leading NGOs involved in this effort included ACT UP, Médecins Sans Frontières (MSF), Health Action International, OxFam, and the Consumer Project on Technology. When MSF won the Nobel Peace Prize in 1999, it donated all of the award money to the Access Campaign.

A typical GCS effort was the November 1999 Amsterdam Statement signed by more than 350 participants, which averred the following:

In the developing world, a lucrative or "viable" market for lifesaving drugs simply does not exist. But clearly what does exist is need. The market has failed both to provide equitably priced medicines and to ensure research and development for infectious disease. This lack of affordable medicines and research and development for neglected diseases is causing avoidable human suffering. Market forces alone will not address this need: political action is demanded.⁵⁶

The coordinator for MSF's Globalization project stated that the Amsterdam Statement served as a guide for the work global civil society on TRIPS and public health.⁵⁷

Transnational activist networks influenced the TRIPS regime through three mechanisms. First, NGOs played a crucial role in raising the issue to governments of all stripes. According to Susan Sell and Aseem Prakash, the NGO network supported and encouraged developing country governments to issue compulsory licenses for life-saving

⁵⁴ Quoted in Barton Gellman, "A Conflict of Health and Profit," Washington Post, 21 May 2000.

⁵⁵ Nathan Ford *et al*, "The Role of Civil Society in Protecting Public Health over Commercial Interests: The Case of Thailand," *The Lancet* 363 (14 February 2004), p. 560.

⁵⁶ Accessed at http://www.accessmed-

msf.org/upload/ReportsandPublications/17122001173935/Amsterdam%20statemt.pdf, 5 August 2005.

⁵⁷ 't Hoen, "TRIPS, Pharmaceutical Patents, and Access to Essential Medicines," p. 34.

drugs. NGOs were particularly crucial in providing legal expertise to developing countries, permitting them to take an active role in TRIPS negotiations. Peter Drahos documents the extent to which the African countries' increased influence within the TRIPS Council was enabled by partnerships with NGOs.⁵⁸

The same GCS coalition also lobbied American and European trade officials by providing information on the connection between TRIPS and the public health crises in the developing world. In 2000, United States Trade Representative Charlene Barshefsky told the *Washington Post*: "Largely it was the activities of ACT-UP and the AIDS activists that galvanized our attention [to the fact] that there was an absolute crisis.... [In the past] I was certainly not aware of this at all." Other USTR and European Commission officials have also acknowledged their ignorance of the public health dimensions of their work prior to the Access Campaign. 60

Second, GCS activists tried to raise public awareness of the issue in the developed world as a means of pressuring political leaders in these countries. Again, there is evidence of success on this front. ACT UP disrupted the official start to Al Gore's 2000 presidential campaign to protest Gore's alleged involvement in pressuring South Africa to strictly enforce the TRIPS accord. The NGO gained additional publicity by disrupting later campaign events. Sell and Prakash observe that by 2001, news stories containing the terms "patents" and "public health" in the same article had increased seven-fold from three years prior. To push the "public health" frame of thinking about IPR and TRIPS, GCS efforts also focused on encouraging non-trade international governmental organizations, such as the World Health Organization, UNAIDS, and the European Parliament to get involved on the issue.

Third, public health advocates worked to combat the messages and *memes* of PhRMA and governments that opposed weakening the enforcement of TRIPS. GCS activists engaged in research designed to counter the claim that patent protection was necessary to fund research and development for new drugs. In the run-up to the Doha

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⁵⁸ Drahos, "Developing Countries and International Intellectual Property Standard-Setting,"

⁵⁹ Gellman, "A Conflict of Health and Profit."

⁶⁰ Anna Lanoszka, "The Global Politics of Intellectual Property Rights and Pharmaceutical Drug Policies in Developing Countries," *International Political Science Review* 24 (May 2003), p. 192.

⁶¹ For a chronology of these events from ACT-UP's perspective, see Mark Milano, Alan Berkman, and David Hoos, "Breaking the Silence: Activist efforts to Improve Global Access to AIDS Medications," paper presented at the 13th International AIDS Conference, Durban, South Africa, July 2000.

⁶² Sell and Prakash, "Using Ideas Strategically," p. 166.

⁶³ 't Hoen, "TRIPS, Pharmaceutical Patents, and Access to Essential Medicines," p. 35-38.

ministerial, both USTR and PhRMA put out repeated statements minimizing the role that patent protections played in hindering the treatment of AIDS in the developing world; GCS activists responded by pointing out the internal contradictions of such a claim. As one activist put it: "If patents in developing countries are not important to Pharma, why so much concern about obtaining and enforcing them?" 64

According to the GCS narrative, this activist campaign led to two tangible and significant policy shifts in the global governance of public health and intellectual property. First, prior to Doha, both the United States and the European Union scaled back efforts to enforce the TRIPS accord against countries affected by the AIDS crisis. Initially, the Clinton administration applied limited economic sanctions and threatened more against South Africa unless that country repealed its Medicines and Related Substances Control Amendment Act of 1997. The law allowed for the compulsory licensing of generic ARVs. The European Commission applied similar pressure. In 2001, the Bush administration filed a complaint with the WTO over Brazil's AIDS program, which relies heavily on competition from generic drug producers.

In both cases, the threats of coercion prompted widespread protests from GCS activists. In the case of South Africa, the Office of the Vice President interceded with the USTR to change American policy. In both cases, the great powers – and PhRMA – retreated from their initial positions and chose not to challenge these domestic laws. In the United States, these changes were codified into a more general policy. In December 1999, President Clinton said in a speech at the Seattle WTO Ministerial declaring that, "the United States will henceforward implement its health care and trade policies in a manner that ensures that people in the poorest countries won't have to go without medicine they so desperately need." In May 2000, this policy was codified into an executive order dictating that the U.S. "shall not seek, through negotiation or otherwise, the revocation or revision of any intellectual property law or policy" for countries in sub-Saharan Africa. The Bush administration reaffirmed this principle in February 2001, and later in the year agreed to negotiate with Brazil rather than pursue WTO enforcement.

The second major achievement was the Doha Declaration itself. Various articles of the original TRIPS accord allowed for "limited exceptions" to stringent IPR

⁶⁴ Frederick Abbott, "The Doha Declaration on the TRIPS Agreement and Public Health," *Journal of International Economic Law* 5 (Spring 2002), p. 485.

⁶⁵ Remarks by President Clinton, 1 December 1999. Accessed at http://usembassy-australia.state.gov/hyper/WF991202/epf402.htm, 10 September 2005.

enforcement, but they were vaguely worded.⁶⁶ The legal uncertainty associated with that issue had deterred many developing countries from even skirting the boundaries of TRIPS for fear of running afoul of either the great powers or a WTO dispute panel. The Doha Declaration greatly reduced (but did not eliminate) that uncertainty. In addition, the agreement also gave least developed WTO members an additional ten-year exemption to the implementation of patent protections of pharmaceutical products.⁶⁷

Experts and media reports interpreted the Doha Declaration as a clear victory for developing countries as opposed to the developed world or PhRMA. The "blowback" of negative publicity for the pharmaceutical sector – caused almost entirely by global civil society – made this outcome inevitable. One reporter concluded: "Going into Doha, U.S. drug companies had become a public relations liability for the cause of preserving patent protection for corporations. Headlines at home and abroad depicted them as heartless profiteers that charged dying, impoverished Africans exorbitant prices for AIDS medicines."68

Analysts also credited transnational activist networks as the pivotal actors responsible for the Doha Declaration. Economist Arvind Panagariya concluded, "The credit for pushing through the Declaration on the TRIPS Agreement and Public Health must go largely to civil society groups from both North and South, which spoke with one voice and rallied behind an undeniably worthy cause." An EU trade expert confirmed that "it is beyond doubt that [the Doha Declaration] has legal value." Reflecting on the policy changes between the Uruguay Round and the Doha round, Prakash and Sell conclude:71

⁶⁶ For example, Article 30 reads in full: "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." Accessed at http://www.wto.org/english/tratop_e/trips_e/t_agm3_e.htm, 1 August 2005.

⁶⁷ "Declaration on the TRIPS Agreement and Public Health," paragraph 7.

⁶⁸ Jeff Faux, "A Trade Deal Built on Sand," *The American Prospect* Online, 4 December 2001. Accessed at http://www.prospect.org/webfeatures/2001/12/faux-j-12-04.html, 8 August 2005. See also Abbott, "Doha and the TRIPS Declaration on Public Health," p. 473.

⁶⁹ Arvind Panagariya, "Developing Countries at Doha: A Political Economy Analysis," *The World Economy* 25 (September 2002), p. 1226.

⁷⁰ Jean Charles Van Eeckhaute, "The Debate on the TRIPs Agreement and Access to Medicines in the WTO: Doha and Beyond," Pharmaceuticals Policy and Law 5 (2002), p. 14.

⁷¹ Prakash and Sell, "Using Ideas Strategically," p. 167.

The NGO network presented a normative frame and proposed policy solutions that the business network opposed. In the end, with its successful strategies of mobilizing a transnational coalition, framing policy problems, disseminating information, grafting its agenda as a solution to policy problems, and exploiting political opportunities... the NGO network has clearly won some substantive victories and brought about normative change in the IPR debate.

Since the Doha Declaration, the United States has publicly proclaimed its restraint in pushing patent protection for pharmaceuticals in its bilateral and regional free trade agreements (FTA). On its web site, the USTR stresses that, "The FTAs we have negotiated similarly contain the flexibility needed in order to address public health crises." FTAs with Chile, Morocco, and Bahrain do not contain any restrictions on compulsory licensing. Typical of these arrangements is the Central American Free Trade Agreement, which includes an understanding specifying that CAFTA's intellectual property provisions "do not affect a Party's ability to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS." The Doha Declaration is also explicitly mentioned in the understanding.

The effect of these shifts in policy on the cost of AIDS drugs was significant. According to Médecins Sans Frontières, the price of most first-line ARVs per patient-year fell from \$10,000 in 2000 to \$150 in 2005. From the GCS perspective, this is a case where actors that possess little in the way of conventional material capabilities were able to alter the preferences of great power actors. GCS activists accomplished this task despite the implacable opposition of multinational corporations with enormous specific assets invested in the status quo ante.

Reinterpreting the shift on intellectual property

⁷² Office of the USTR, "Fact Sheet on Access to Medicines," 9 July 2004. Accessed at http://www.ustr.gov/Document_Library/Fact_Sheets/2004/Fact_Sheet_on_Access_to_Medicines.html, 9 August 2005.

⁷³ Office of the USTR, "Understanding Regarding Certain Public Health Measures," 5 August 2004. Accessed at http://www.ustr.gov/assets/Trade_Agreements/Bilateral/CAFTA/CAFTA-DR_Final_Texts/asset_upload_file697_3975.pdf, 9 August 2005.

⁷⁴ http://www.accessmed-msf.org/prod/publications.asp?scntid=28620052030274&contenttype=PARA&, accessed 9 August 2005.

The narrative and evidence put forward to support the GCS paradigm on this issue is compelling. Interviews with USTR officials confirm that U.S.-based NGOs acted as an effective "fire alarm" in alerting trade officials to the AIDS crisis in Africa.⁷⁵ However, as discussed previously, prior claims of GCS effects have suffered from one of two flaws – a neglect of alternative explanations and an overestimation of the policy shift. This section considers whether these flaws are also present in the apparent GCS victory in the Doha Declaration.

Are there alternative explanations for the shift in great power behavior? In the case of the United States, one alternative explanation exists for the shift in preferences – viewing infectious diseases as a transnational threat to national security. Over the course of Clinton's second term, the national security bureaucracies in general, and the National Security Council in particular, devoted an increasing amount of attention to the problem of transnational threats. Threats ranging from terrorism to financial contagion to infectious diseases had the potential to breach U.S. borders. Almost as disconcerting was the effect these transnational threats could have on regional stability in areas with weak or failing states. In the case of HIV/AIDS, security experts became increasingly concerned that the spread of infection among elite members of the least developed countries threatened to erode the ability of the state to govern. The shadow of the state to govern.

The U.S. concern with the transnational threat posed by infectious diseases predates the GCS campaign for flexibility on intellectual property rights. In June 1996 President Clinton issues a Presidential Decision Directive addressing the threat of infectious diseases, stating, "Emerging infectious diseases such as Ebola, drug-resistant tuberculosis, and HIV/AIDS present one of the most significant health and security challenges facing the global community." HIV/AIDS was raised as a national security matter at both the CIA and the NSC prior to the protest actions by GCS activists in 1999.

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⁷⁵ On the role that interest groups and NGOs can play as "fire alarms" in international negotiations, see Helen V. Milner, *Interests, Institutions, and Information: Domestic Politics and International Relations* (Princeton: Princeton University Press, 1997).

⁷⁶ David Rothkopf, *Running the World* (New York: Public Affairs, 2005), p. 364 and 382; See, more generally, Richard Clarke, *Against All Enemies* (New York: Free Press, 2004).

⁷⁷ For a recent exposition of the interrelated security threats created by the spread of AIDS, see Laurie Garrett, *HIV and National Security: Where Are the Links?* (New York: Council on Foreign Relations, 2005).

⁷⁸ PDD NTSC-7, "Addressing the Threat of Infectious Diseases," 12 June 1996. Accessed at http://www.fas.org/irp/offdocs/pdd ntsc7.htm, 13 September 2005.

The concern about the transnational threat from disease also appeared in the national security strategies. The 1999 U.S. National Security Strategy stated:⁷⁹

Environmental and health problems can undermine the welfare of U.S. citizens, and compromise our national security, economic and humanitarian interests abroad for generations. These threats respect no national boundary. History has shown that international epidemics, such as polio, tuberculosis and AIDS, can destroy human life on a scale as great as any war or terrorist act we have seen.

A January 2000 National Intelligence Estimate concurred:80

New and reemerging infectious diseases will pose a rising global health threat and will complicate US and global security over the next 20 years. These diseases will endanger US citizens at home and abroad, threaten US armed forces deployed overseas, and exacerbate social and political instability in key countries and regions in which the United States has significant interests.

By the late nineties, stopping the global spread of HIV/AIDS was not merely a priority of global civil society – it was a priority for national security specialists as well. Vice President Gore's National Security Advisor, Leon Fuerth, phrased the administration's evolving position as "a sense of national interest informed by ethics." He concluded: "We approached the HIV problem from a sense what was right to do and what was in our interest to do, and we had no problem with seeing these as congruent." 81

One crude measure of this shift in national security focus can be seen in the attention devoted to public health vs. intellectual property in the series of National Security Strategies promulgated by the Clinton and Bush administrations between 1996 and 2001. A new NSS was introduced every year between 1996 and 2001. Because the NSS is designed for a national security audience, and not distributed to non-governmental actors prior to publication, one would expect GCS influence over the drafting process to be minimal. As Table 1 demonstrates, there was a noticeable shift over time emphasizing public health in general – and AIDS in particular – as a national security issue. In

⁷⁹ White House, "A National Security Strategy for a New Century," Washington, DC, December 1999, p. 3. Accessed at http://www.fas.org/man/docs/nssr-1299.pdf, 15 August 2005.

⁸⁰ National Intelligence Council, "The Global Infectious Disease Threat and Its Implications for the United States," January 2000. Accessed at http://www.cia.gov/cia/reports/nie/report/nie99-17d.html, 13 September 2005.

⁸¹ Interview with Leon Fuerth, 15 September 2005.

contrast, concerns about intellectual property rights enforcement waned. As the 2001 numbers show, this concern was not strictly a partisan one – HIV/AIDS remained a priority concern of the Bush administration as well.⁸²

[Table 1 about here]

Global civil society was neither directly nor indirectly responsible for the emergence of this "transnational threat" frame. There is no mention of the national security implications of infectious diseases in the Amsterdam Statement, or in similar documents. A search of online press release archives of the significant NGOs involved in the Access Campaign also failed to turn up any positive use of the transnational threat argument. This may have been because such arguments were seen as insufficiently altruistic. Indeed, the president of MSF's International Council, in a June 2000 speech, deplored the use of any national security logic to promote TRIPS flexibility – while still acknowledging the role that security interests played in the policy shift:

Now that the sufferings and diseases of the poor are a 'threat' to national security and to expanding global markets, there is political interest. Well this is not good enough. We must take this new-found political interest, and not allow a fiscal and state-security agenda to drive our agenda, which is one that is irreducibly committed to social justice.⁸³

The national security explanation for the shift in U.S. preferences can also be seen in the bureaucratic origins for the shift in the Clinton administration's position on AIDS and TRIPS. When South Africa passed its generic ARV measure, the USTR advocated moving South Africa to a "priority watch list" under section 301 of U.S. trade law. However, both Gore's staff *and* the National Security Council staff opposed the move on national security grounds – prior to the protests of Gore's campaign. ⁸⁴ Contrary to claims made by AIDS activists and GCS scholars that Gore needed to be persuaded to support their cause, both press reports at the time and interviews conducted with former trade

⁸² The decline in mentions in the 2001 document can be traced to the decline in length of the overall document.

⁸³ Dr. James Orbinski, speech to the Health Forum, 14 June 2000. Accessed at http://www.msf.org/msfinternational/invoke.cfm?component=article&objectid=B6533B59-3EBB-4416-81F1367425329FE3&method=full_html, 13 September 2005.

⁸⁴ Gellman, "Gellman, "A Conflict of Health and Profit"; interviews with NSC and USTR officials.

officials confirm that Gore "led the way" in opposing any move towards economic coercion against South Africa. When asked about the role that activists and protestors on the presidential campaign trail played in the resolution of that case, Fuerth replied: "You could draw the conclusion that it was the demonstrations that brought us to closure, and I'm not sure I can disprove that, *but it is simply not true*." Both Gore and Fuerth cited the transnational threat posed by AIDS as a constant foreign policy theme throughout the 2000 campaign.⁸⁷

The anthrax scare in the fall of 2001 also reinforced the transnational threat frame. The spread of anthrax through the mail to multiple American cities – including Washington, DC – stirred calls to license the generic manufacture of Cipro, an antibiotic patented by Bayer. Health officials in both Canada and the United States threatened to bypass Bayer's patent to ensure sufficient quantities of the antibiotic could be procured affordably. Both governments eventually backed down from that threat after negotiations with Bayer. In the run-up to Doha, however, the incident caused negotiating difficulties for the United States; the USTR's office to explicitly address what the Doha Declaration would later reiterate:

Given the discovery of anthrax in New York, Florida, and the Washington, DC metropolitan area, and the risk of individuals being infected with a potentially deadly virus, the United States would be permitted under TRIPs to exercise its rights to go outside the patent process.... These flexibilities are not limited to the United States. They are available to every other member of the WTO.⁹¹ (emphasis added)

Concerns about national security help to explain why the United States scaled back its eagerness to unilaterally enforce the strictest interpretation of the TRIPS accord against countries suffering from epidemic levels of AIDS.

⁸⁵ Ibid.; see also Jonathan Weisman, "Gore's Campaign Disrupted over South African AIDS Drugs," Baltimore Sun. 22 June 1999.

⁸⁶ Emphasis added. Quoted in Gellman, "A Conflict of Health and Profit."

⁸⁷ See, for example, "Vice President Gore's Remarks on AIDS to UN Security Council," 10 January 2000, at http://www.aegis.com/news/usis/2000/US000102.html (accessed 9 August 2005).

⁸⁸ Lanoszka, "The Global Politics of Intellectual Property Rights," p. 1823.

⁸⁹ Kristin Johnson, "Thompson May Seek to Void Cipro Patent if Talks Fail," Bloomberg, 23 October 2001

⁹⁰ Interview with former USTR official.

⁹¹ Office of the USTR, "TRIPs and Health Emergencies," 10 November 2001. Accessed at http://www.ustr.gov/Document_Library/Press_Releases/2001/November/TRIPs_Health_Emergencies.html, 10 August 2005.

The USTR statement also reveals, however, that the United States did not think the Doha Declaration was necessary. The American negotiating position was that the original TRIPS accord *already* contained public health exceptions for epidemics and the like. Consistent with the national security frame, the U.S. position was that exceptions to TRIPS should apply only to poor countries with weak state institutions that suffer from epidemics – but the carve-out should not go any further. The European Commission's position on the TRIPS accord was similar. GCS advocates, in contrast, wanted as broad a "public health" exception to TRIPS as possible, covering any and all forms of illness.

Why, then, did the great powers accede to a declaration at Doha that contained such broad public health language? GCS activity had no direct effect on the United States; multiple USTR officials have refuted the notion that they felt pressure to cut a deal because of NGO activities. GCS scholars counter that civil society influence in this event was indirect; transnational activists influenced the position of developing country members. The sheer number of supporting countries – and the improved coordination among the developing bloc – isolated the great powers and forced the United States and European Union to shift their positions.

Again, this is factually plausible, 95 but conceptually incomplete. In the past and present both the United States and the European Union have run into roadblocks at universal-membership IGOs. At these junctures in the past, great powers have demonstrated a clear willingness to either act unilaterally or shift fora to a more sympathetic IGO. 96 This is especially true of the current Bush administration. The important counterfactual question worth asking is why the great powers agreed to the Doha Declaration when there were alternative strategies outside the WTO process.

There are two parts to this answer: Doha and its aftermath. Although there are always some costs to forum-shopping, those costs were uniquely prohibitive for the great

⁹² See, in particular, articles 7, 8, 30, and 31 of the original TRIPS agreement.

European Commission, "Agreement on Intellectual Property Rights Relating to Trade and Pharmaceutical Patents," accessed at http://europa.eu.int/scadplus/leg/en/lvb/l21168.htm, 11 August 2005.
 Interviews and e-mail exchanges with current and former USTR officials, June-August 2005.

⁹⁵ Though it should be noted that at the time of the negotiations, the coherence of the developing country bloc was open to question. The *Financial Times* reported during the Doha conference that, "Western negotiators say satisfying developing countries' grievances is made more difficult because they are so diverse and often poorly defined. 'They do not have a very clear position. Trying to make progress is very frustrating,' one European official said." Guy De Jonquieres and Frances Williams, "Poor Countries raise hurdle at WTO," *Financial Times*, 9 November 2001.

⁹⁶ Drezner, Who Rules?; Stephen D. Krasner, Structural Conflict (Berkeley: University of California Press, 1985); Krasner, "Global Communications and National Power: Life on the Pareto Frontier," World Politics 43 (April 1991): 336-366.

powers at the time of the Doha ministerial – for reasons that had little to do with the Access Campaign. In the aftermath of the September 11th attacks, the United States was determined to launch a trade round at Doha in order to counter impressions that the terrorist attacks would weaken the process of economic globalization and/or undercut U.S. leadership.⁹⁷ The failure to launch a trade round at Seattle three years earlier also increased the stakes at Doha for the ability of the WTO regime to advance trade liberalization. Finally, the ability of the great powers to shift fora on intellectual property from World Intellectual Property Organization (WIPO) to the WTO in the Uruguay round made it that much more difficult to try and shift governance structures less than a decade later. Ironically, the efforts to create enforceable "hard law" on IPR in the first place also raised the costs on future forum-shifting.⁹⁸ Because the Americans and Europeans had invested so much in the WTO regime, any legal weakening of that regime would be costly to them. One European Commission trade negotiator observed after Doha that, "in the absence of any Declaration on public health, *de facto* non-compliance by several developing countries was a real risk."⁹⁹

The uniquely binding venue and timing of Doha prevented the United States from substituting across governance structures. The multiplicity of linked trade issues also benefited the developing country position. Because so many issues at Doha were being negotiated at the same time – textiles, agricultural subsidies, investment, procurement, the environment, etc. – the developing countries were able to link issues to ensure concessions on TRIPS. Because the U.S. was committed to securing agreement at Doha to launch a new trade round, USTR officials decided early on that making concessions on IPR early on would increase the odds of success. OAS Haochen Sun observes, WTO] members came to understand that no broad negotiating mandates such as investment and competition would emerge from the conference in the absence of a meaningful result on medicines.

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⁹⁷ Panagariya, "Developing Countries at Doha," p. 1205.

⁹⁸ On this point, see Kenneth Abbott and Duncan Snidal, "Hard and Soft Law in International Governance," *International Organization* 54 (Summer 2000): 421-456.

⁹⁹ Eeckhaute, "The Debate on the TRIPs Agreement and Access to Medicines in the WTO," p. 22.

¹⁰⁰ According to one interview with a former USTR official, U.S. Trade Representative Robert Zoellick explicitly made this calculation in signing off on the Doha declaration.

¹⁰¹ Haochen Sun, "The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health," *European Journal of International Law* 15 (February 2004), p. 136. See also Guy De Jonquieres, "All night haggling in Doha leads to agreement," *Financial Times*, 15 November 2001.

GCS actors and developing country governments were astute to exploit the unique opportunity presented by Doha. The uniqueness, however, should be stressed. In the fall of 2001, great powers faced extreme values of two control variables: a) higher costs for forum-shopping than normal; and b) an urgent need for forward momentum on WTO trade negotiations. This suggests that, like domestic analyses of "policy windows," there are moments when GCS actors can seize the stage at the global level. However, such policy windows are not a function of non-state actors, and over time they can fade.

On the other hand, if the GCS argument about the spread of norms is correct, then one would expect to see continued adherence to the norm developed at Doha. Process-tracing the post-Doha developments presents an ideal testing venue. If the hypothesis about global civil society narrative holds, then a norm cascade should take effect. The result would be the continued diffusion and internalization of the public health *meme* in the global governance of intellectual property rights. If more conventional arguments about world politics hold up, we should see the great powers acting to restrict and constrain the public health exception to their preferred level – flexibility on IPR in the case of epidemics affecting the poorest countries.

The evidence strongly suggests that as the constraints faced by the great powers at Doha have lessened, the regulation of IPR has shifted back towards the great powers' preferred set of outcomes. One policy response was to push for stronger IPR protections than TRIPS – referred colloquially as "TRIPS-plus" – outside of the WTO framework. The proliferation of bilateral free trade agreements (FTAs) in recent years has given the great powers an opportunity to use their market power to ratchet up IPR standards in the developing world. The European Commission and the European Free Trade Area have both inserted TRIPS-plus IPR provisions into their free trade agreements with developing countries. EU agreements with Tunisia and Morocco, for example, include provisions requiring IPR protection and enforcement "in line with the highest international standards." The United States has been equally persistent in this practice. Table 2 demonstrates the TRIPS-plus IPR provisions in U.S. trade agreements that have been

¹⁰² John W. Kingdon: Agendas, Alternatives, and Public Policies.

¹⁰³ Peter Drahos, "Bilateralism in Intellectual Property," Oxfam Research Paper, FULL CITE.

¹⁰⁴ Ibid., p. 13; see also European Commission, "EU Strategy to Enforce Intellectual Property Rights in Third Countries," MEMO/04/255, 10 November 2004. For information on EFTA trade pacts, see Julien Bernhard, "Deprive Doha of All Substance," August 2004, at http://www.evb.ch/cm_data/Deprive_Doha.pdf (accessed 12 August 2005).

ratified since 2000.¹⁰⁵ The U.S. has also used the carrot of bilateral investment treaties in order to secure bilateral intellectual property agreements that can include TRIPS-plus agreements.¹⁰⁶

How do these TRIPS-plus provisions in FTAs jibe with the USTR trumpeting "Doha-friendly" understandings and side-agreements associated with these FTAs? Oxfam argues that these understandings have "interpretive value only and will not change the binding TRIPS-plus provisions" in the FTAs themselves. ¹⁰⁷ Frederick Abbott argues that these side agreements "are drafted in a substantially more restrictive way" than the Doha Declaration itself. ¹⁰⁸ At a minimum, the combination of legal texts introduces legal uncertainty, constraining the flexibility of the TRIPS accord desired by global civil society. In effect, the legal arrangements shift the status quo to the U.S.-preferred outcome; one in which flexibility is only invoked in times of crisis epidemics.

[Table 2 about here]

As Table 2 demonstrates, the most prominent of the TRIPS-plus provisions is the protection of test data. To satisfy government regulations, drug manufacturers are required to undergo significant amounts of testing to demonstrate safety and effectiveness, imposing additional costs on first-mover manufacturers. Data protection prevents other drug manufacturers from relying on that data to obtain approval for drugs that are chemically identical to the original patent-holder. The United States ensures data protection for five years; EU member states offer between six to ten years. In 2005, the USTR stated in its Special 301 Report to Congress that data protection would be "one of the key implementation priorities" for the executive branch. The report went on to identify deficiencies in data protection in more than twenty countries, including China,

¹⁰⁵ How do these TRIPS-plus provisions jibe with the understandings and side-agreements trumpeted by the USTR's web site? This remains unclear. Oxfam argues that these understandings have "interpretive value only and will not change the binding TRIPS-plus provisions" in the FTAs themselves. Frederick Abbott argues that these side agreements "are drafted in a substantially more restrictive way" than the Doha Declaration itself. At a minimum, the combination of legal texts introduces legal uncertainty, constraining the flexibility of the TRIPS accord desired by global civil society. In effect, the legal arrangements shift the status quo to the U.S.-preferred outcome; one in which flexibility is only invoked in times of crisis epidemics.

¹⁰⁶ Drahos, "Bilateralism in Intellectual Property," p. 6.

¹⁰⁷ Oxfam, "Undermining access to medicines: Comparison of five US FTAs," Oxfam Briefing Note, July 2004

¹⁰⁸ Frederick Abbott, "The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health," *American Journal of International Law* 99 (2005), p. 352.

India, Russia, Mexico, and Thailand.¹⁰⁹ The continued use of Special 301 to threaten trade sanctions against countries perceived as violated intellectual property rights is a powerful lever through which the U.S. has tried to advance its preferences. In the past, even an implicit threat of economic coercion has been sufficient to force dependent allies into altering their regulations on these issues.¹¹⁰

Both proponents and opponents of patent protections on pharmaceuticals agree on the post-Doha constraints placed on the "public health" frame in U.S. trade policy. One former USTR negotiator commented, "I think that individual NGO efforts got spectacular media coverage, but I'd question their real impact against the bulk of U.S. achievements since the Uruguay round."111 Many of the same GCS analysts who claimed a victory at Doha acknowledge that the proliferation of "TRIPS-plus" provisions in free trade agreements undercuts the public health norm established at Doha. 112 Frederick Abbott, who under the auspices of the Quaker United Nations Office provided legal assistance to developing countries in TRIPS negotiations, concludes that the developing world and NGOs have, "substantially increased their negotiating effectiveness in Geneva but have yet to come to grips with the U.S. forum-shifting strategy." In a May 2004 letter to U.S. Trade Representative Robert Zoellick, approximately 90 NGOs protested the inclusion of these TRIPS-plus provisions in FTAs, stating, "Intellectual property provisions in US free trade agreements already completed or currently being negotiated will severely delay and restrict generic competition... through complex provisions related to market authorization and registration of medicines."114

A final move by the great powers has been to try and narrow the scope of the Doha Declaration's applicability. What Doha left unresolved was how the provision on compulsory licensing would apply to countries that lacked domestic pharmaceutical industries. The declaration promised, "to find an expeditious solution to this problem" over the next twelve months. 115 NGOs and developing countries wanted the widest

¹⁰⁹ Office of the USTR, "Special 301 Report," April 2005. Quotation from p. 6.

¹¹⁰ Daniel W. Drezner, "The Hidden Hand of Economic Coercion." *International Organization* 57 (Summer 2003): 643-659; Drezner, "Outside the Box: Explaining Sanctions in Pursuit of Foreign Economic Goals." *International Interactions* 26 (Summer 2001): 379-410.

¹¹¹ E-mail communication from former USTR official, 5 August 2005.

¹¹² Sell, Private Power, Public Law, chapter six; Abbott, "The WTO Medicines Decision."

¹¹³ Abbott, "The WTO Medicines Decision," p. 317.

¹¹⁴ "Letter from 90 NGOs to U.S. Trade Representative Robert Zoellick ," 27 May 2004. Accessed at http://www.cptech.org/ip/health/trade/ngos05272004.html, 11 August 2005.

^{115 &}quot;Declaration on the TRIPS Agreement and Public Health," paragraph 6.

possible leeway granted to developing countries. The United States and European Union sought to limit the extent of the concessions made on TRIPS in the Doha Declaration to the least developed countries and low-income developing countries. The U.S. went so far as to push for limiting TRIPS flexibility to HIV/AIDS, tuberculosis, and malaria, excluding the "other epidemics" language from the Doha Declaration. 117

Like Doha, and in contrast to the original TRIPS accord, NGOs were heavily involved in these negotiations between November 2001 and August 2003. Unlike Doha, however, the United States did not feel compelled to secure an agreement at a particular time. As a result, the USTR blocked an agreement from being reached by the desired deadline because of concerns over the draft language. The end result was in rough accord with great power preferences: The scope of importation primarily benefited the least developed countries, with strict limits put on parallel importation in developing countries. Procedural barriers limit but do not exclude the use of TRIPS flexibilities by other developing countries, conforming to American and European preferences.

Reviewing the negotiation history, Duncan Matthews concluded: "ultimately the outcome, characterized by the dominance of the US and the EU as key international actors, coupled with the reluctance of developing country governments to ultimately oppose the US approach in the face of negotiating fatigue and the threat of bilateral trade sanctions, is remarkably familiar and repeats the pattern of earlier negotiations."

Great power behavior before and after Doha would suggest very little internalization of global civil society's preferred "public health" frame in thinking about TRIPS. However, one possibility is that the United States government has adopted a different variation of the same frame. For example, in discussing the enforcement of intellectual property rights, the Office of the USTR repeatedly stresses the public health benefits that accrue from intellectual property protections. A July 2004 USTR fact sheet points out that because of the TRIPS-plus protections in the Jordan FTA, drug innovation in that country dramatically increased. Economists and lawyers have argued that more

¹¹⁶ Duncan Matthews, "WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health," *Journal of International Economic Law* 7 (Winter 2004): 73-107. ¹¹⁷ The USTR was concerned that the "other epidemics" language would be broadly construed to include "lifestyle" diseases such as obesity. Ibid., p. 86.

¹¹⁸ Ibid., p. 84; Abbott, "The WTO Medicines Decision," p. 328.

¹¹⁹ Matthews, "WTO Decision on Implementation of Paragraph 6," p. 105; for a more GCS-friendly interpretation, see Abbott, "The WTO Medicines Decision."

Office of the USTR, "Fact Sheet on Access to Medicines," July 2004. Accessed at http://www.ustr.gov/Document_Library/Fact_Sheets/2004/Fact_Sheet_on_Access_to_Medicines.html, 9

vigorous IPR enforcement in the developing world would spur medical advances to treat diseases in those countries.¹²¹ In the 2005 Special 301 report, there is similar language about medical innovations with regard to the marketing of pharmaceuticals.

Not surprisingly, the key players in the GCS campaign behind the Doha Declaration vigorously dispute these assertions.¹²² It is beyond the scope of this paper to determine which frame has greater merit. However, what matters is the emergence of an alternative frame to view IPR policy with regard to health. Some scholars argue that this leads to a battle between business and NGO networks on the issue.¹²³ While true, this observation omits an important implication. By playing one network off of the other, the state can actually increase its policymaking autonomy. As a result, the post-Doha regime on IPR closely conforms to great power preferences.

Conclusions

Scholars have identified several instances in which global civil society has influenced global governance outcomes. Critical assessments of these cases, however, have revealed that in much of the GCS literature, alternative causes are neglected and the magnitude of the policy outcome are exaggerated. This paper has examined whether these tropes are also present in GCS analyses of the post-TRIPS debate on intellectual property and public health, crystallized by the Doha declaration on the TRIPS agreement and public health. Because this represents a "tough test" of global civil society arguments, this case is pivotal to debates about the role on non-state actors in world politics.

The evidence suggests that global civil society did play a role in shifting policy on intellectual property rights – but the role has been exaggerated both before and after the Doha declaration. GCS scholars argue that the U.S. shifted its policy because transnational activists created a new normative frame of public health to view the

¹²¹ Alan Sykes, "TRIPs, Pharmaceuticals, Developing Countries, and the Doha 'Solution'" *Chicago Journal of International Law* 3 (Spring 2002).

August 2005.

¹²² Oxfam, "Undermining access to medicines,"; Hamed El-Said and Mohammed El-Said, "TRIPS, Bilateralism, Multilateralism & Implications for Developing Countries: Jordan's Drug Sector," *Manchester Journal of International Economic Law* 2 (April 2005).

¹²³ Prakash and Sell, "Using Ideas Strategically."

problem. While there is little doubt that GCS activists did push a public health frame, this version of events is incomplete – it assumes a world in which only these two frames existed. National security experts increasingly deployed a transnational threat frame over the same period, which allowed them to intervene on the TRIPS issue in the late nineties and in the run-up to the Doha declaration. Transnational activists were pushing governments towards recognizing the public health crises in the developing world – but they were pushing key governments in a direction that they already wanted to go.

After Doha, both the United States and the European Union acted within and without the World Trade Organization to place clear boundaries on IPR flexibilities. Both economic great powers enshrined "TRIPS-plus" elements into bilateral investment treaties and free trade agreements. The U.S. in particular evinced a willingness to use unilateral threats of economic coercion to enforce intellectual property on pharmaceuticals as well. Two years after the Doha declaration, a subsequent agreement on the importation of generic drugs applied some limitations on the scope of the declaration. Over time, the United States government embraced the "public health" frame, but believed GCS-preferred policies should be limited to least developed countries and/or acute epidemics such as HIV/AIDS. The U.S. also used the "public health" frame to argue for more stringent IPR protections after Doha.

Stepping back, post-Doha events do not mean that GCS activity had no effect on this policy shift, but it does suggest sharp constraints on the ability of global civil society to inject new norms into global public policy. Governments can clearly adapt to the introduction of new ideas, but also assist in the "mutation" of such ideas to suit pre-existing purposes.¹²⁴

The obvious conclusion to draw from this case is that GCS influence has been overrated. And yet, going forward there are two final caveats to consider. First, it is possible that elements of global civil society have redirected their focus on this issue away from states and more towards pressuring the pharmaceutical firms into donating life-saving drugs. This would be an example of "world civic politics" at work. The second caveat is the possibility that non-state actors have a longer-run plan of action than is commonly thought. GCS efforts have a dynamic component to them. One stated goal of global civil society is to convince governments to accept certain sets of norms – but

¹²⁴ Daniel W. Drezner, "Ideas, Bureaucratic Politics, and the Crafting of Foreign Policy." *American Journal of Political Science* 44 (October 2000): 733-749.

the spread of norms is a lengthy process. It is possible that GCS activity on pharmaceutical patents is still in the initial stages of socialization, and will achieve more substantive policy shifts over time/

The problem with this theory of norm change, of course, is that it is impossible to falsify. Would the inability of GCS efforts to ensure the spread of a particular norm indicate failure, or merely the premature assessment of an emergent norm? While non-falsifiable, however, this argument is not necessarily wrong. This leads to an intriguing possibility about the future of intellectual property rights and public health: it is possible that great powers will continue to win most of the major policy skirmishes in the fight, while still losing the war.

TABLE 1

ALTERNATIVE FRAMES IN THE NATIONAL SECURITY STRATEGY¹²⁵

Year	Mentions of "AIDS" or	Mentions of	Mentions of "intellectual
	"public health"	"transnational threat"	property" or "patents"
1996	3	1	3
1997	1	6	2
1998	5	7	9
1999	13	6	4
2000	18	6	5
2001	11	3	1

TABLE 2

IPR PROVISIONS IN AMERICAN FTAs, 2000-2005¹²⁶

FTA	Mandatory patent	Protection of	Marketing	Limits on parallel imports or
	extensions	test data	restrictions	compulsory licensing
Jordan		X		X
Singapore	X	X	X	X
Chile	X	X	X	
Australia		X	X	X
Morocco	X	X	X	X
CAFTA	X	X	X	

¹²⁵ Searchable documents retrieved from http://www.fas.org/man/doctrine.htm#nation (1996-1999); http://www.au.af.mil/au/awc/awcgate/nss/nss_dec2000_contents.htm (2000), and http://www.whitehouse.gov/nsc/nssall.html (2001).

¹²⁶ Sources: Committee on Government Reform minority staff, U.S. House of Representatives, *Trade Agreements and Access to Medications Under the Bush Administration*, Washington, DC, June 2005; Consumer Project on Technology, "Health Care, Regional Trade Agreements, and Intellectual Property," accessed at http://www.cptech.org/ip/health/trade/, 11 August 2005.