Embedded NGOs and the Doha Development Round: Assessing the Role of NGOs in the EC's TRIPS and Access to Medicines Negotiations*

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Abstract

The multilateral trade regime has changed dramatically in character, scope, and intensity since the conclusion of the Uruguay Round of Multilateral Trade Negotiations in 1995. Trade negotiations have become infinitely more complex and effective participation requires sophisticated technical and legal expertise. These developments are accompanied by the emergence of new actors who are mobilizing, not to ensure particular sectors are protected or insulated from the costs of trade liberalization, but to demand that trade-related decisions-making processes involve broader civil society. "Embedded" non-governmental organizations (NGOs) are working to ensure trade rules reflect broader social values and purposes of entire communities and they are responding to dramatic knowledge and power asymmetries in the multilateral trade regime. I examine how these dynamics are playing out in the European Union's external trade policymaking process by looking at the role of Non-Governmental Organizations (NGOs) in the formulation of the European Communities' (EC) position on TRIPS and Access to Medicines. I argue that although there is clear potential for NGOs to represent citizens' demands, constitute a basic form of popular representation and hold decision-makers accountable to a broader public, the prevailing legal/liberal episteme in the international trade regime hamstrings their efforts to ensure the rules pursue just, equitable and fair ends, rendering governance in this area unsustainable. Since improvements on the input side of policymaking alone cannot alter the power dynamics in the international trade regime, NGOs are best advised to build up their strategic policy capacity to help developing and least developed countries formulate, articulate and defend autonomous policy choices.

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I. Introduction

Do more open trade policymaking processes that include non-governmental entities lead to a stronger, more legitimate, and qualitatively enhanced international trade system? In the European Union, do improvements in participatory and access conditions for NGOs result in more legitimate external trade policymaking as many would expect? The findings here represent one stage in a wider research project designed to study whether NGOs have the potential to bring democracy, justice and fairness to post-national governing arrangements. I am especially concerned with whether NGOs can alter patterns of empowerment in the international trade regime. This paper investigates these questions through an examination of the role of NGOs in the formulation of the EC's position on Trade Related Intellectual Property Rights (TRIPS) and Access to Medicines between 1998 and 2008.

A burgeoning body of literature focuses on the emergence and role of Global Civil Society (GCS) in international relations.[1] Scholars are concerned with the wide ranging impact of GCS on global governance[2] and on the establishment, dissemination and enforcement of global norms,[3] in the areas of human rights,[4] environment,[5] landmines,[6] and women's rights[7] amongst many others. They are also concerned with the consequences of the emergence of GCS for state sovereignty.[8] Other common denominators include the belief that GCS can and does represent global citizens' demands, constitutes a basic form of popular representation, and can hold decision-makers accountable, especially through "naming and shaming tactics."[9] In this paper, I challenge a theoretical perspective on public policymaking called Cosmopolitanism. Grounded in democratic and normative theory, it conceives of GCS and NGOs in particular, as conduits for democracy and social justice in global and/or regional governance.

I argue that although NGOs have been instrumental in providing education, raising awareness, and giving a voice to broader societal concerns about the social, health-related and environmental aspects of proposed external trade deals, they cannot determine policy outcomes in this arena. Epistemes, the deepest level of the ideational world, dominate here. NGOs succeed only when their attempts to achieve more democratic, just, equitable and fair external trade policies in the EU conform broadly to the dominant legal/liberal episteme. When they seek to overrule that episteme, they fail.

Following the conclusion of the Uruguay Round of Multilateral Trade negotiations in 1994 and the subsequent entry into force of the Agreement on Trade-Related Intellectual Property Rights (TRIPS) in 1995, NGOs waged a sustained campaign aimed at ensuring the primacy of public health over

[1] For a discussion of the emergence of Global Civil Society see Kaldor et al 2005; Boli and Thomas 1999; Wapner 1995; Florini 2000.
[2] See for instance, O'Brien et. al 2000; Higgott, Underhill and Bieler 2000, esp. part IV; Weiss and Gordenker 1996;
[3] For a discussion of the dynamics of global norms see Finnemore and Sikkink 1999; Clark 2001; Klotz 1995.
[4] See for instance, Keck and Sikkink 1998; Risse, Ropp and Sikkink 1999.
[5] Wapner 1995, 2002; Corell and Betsil 2001a, 2001b; Humphreys 2004.
[6] Williams 1999; Price 1998; Rutherford 2000.
[7] Clark et. al 1998; Berkovitch 1999.
[8] See for instance Falk 1995.
[9] Archibugi 2000, 146.

intellectual property rights and characterized by demands for less stringent Intellectual Property Rights (IPR) enforcement and access to affordable medicines for all.[10] The global Access to Medicines movement is heralded by scholars and activists alike as evidence of NGOs' ability to influence international public policy. Rather than focus on the international dimension of this campaign, as much of the existing literature on the subject has done, this paper traces the role of NGOs in the formulation of the European Communities' (EC) position on trade related intellectual property rights and access to medicines.

The European Union stands out amongst major trading powers for its significant and dramatic response to new demands for access and participation by non-state actors, particularly in the area of external trade policymaking. Since the conclusion of the Uruguay Round of Multilateral Trade Negotiations, CSOs, including NGOs, have experienced sustained, aggregate improvements in participatory and access conditions in the EU's external trade policymaking process. Against the backdrop of these burgeoning new opportunities, NGOs working on the TRIPS: Access to Medicines issue became key interlocutors in Europe beginning in early 2001. They became actively and directly engaged in policy discussions with EU technocrats in the run up to the Doha Declaration in November 2001. In this paper, I examine whether changes in the political opportunity structure for these actors results in more legitimate external trade policymaking in Europe. Given the international renown of the Access Campaign and the deeply institutionalized relationship of NGOs with EU policymakers, this case should constitute an "Easy Test" for Cosmopolitans.

The following analysis proceeds to trace the role of NGOs and the development of the EC's position on TRIPS: Access to Medicines since the conclusion of the Uruguay Round of Multilateral Trade Negotiations in three parts. First, I briefly outline the theoretical framework of this analysis. Second, I examine the development of the EC's position leading up to the 2001 Doha Declaration and the role played by NGOs in educating both the public and EU-level policymakers about the links between stringent IPR protection and the AIDS crisis in Africa. Third, I examine efforts to solve the so-called "Paragraph 6" problem left over from the Doha Declaration. Two key policy developments are of particular relevance here, namely the August 30 Decision and the Protocol of TRIPS Amendment Concerning Article 31*bis*.[11]

Despite clear improvements in procedural legitimacy, early optimism regarding the power of NGOs to bring about substantive, normative changes in the international IPR regime was premature. The evidence, particularly following the Doha Declaration in 2001, suggests that EU policymakers acquiesced to certain NGO demands by making incremental (at least as far as developing and least developed countries were concerned) changes in the least vital areas or by clarifying already existing rules in the international IPR regime to maintain a forward momentum in WTO trade negotiations. Once the pressure from NGOs lessened and the issues became more technical, EU policymakers shifted back to their preferred set of outcomes on IPR. Experts and technocrats, not NGOs, were empowered in the external trade policymaking process to maintain and reinforce the status quo. As the issue became more complex and technical by virtue of the so-called Paragraph 6

[10] 'Access Campaign' in the remainder of this paper refers to the general movement of NGOs, health advocates and AIDS activists and not to the MSF-led Access Campaign, unless otherwise specified.
For comprehensive overviews of this campaign see 't Hoen 2002, 2009; Sell and Prakash 2004.
[11] '*bis'* refers to an addition to an existing Article. In this case, it refers to an addition to TRIPS Article 31.

problem, experts and technocrats gained greater functional authority to find a solution that 'fit' inside and, indeed, reproduces the legal/liberal episteme.

II. Theoretical Framework

Clear indicators are required to evaluate whether the growing involvement of global, embedded NGOs works to improve the legitimacy of policymaking. I borrow insight from the recent proliferation of IR literature that takes a moral or principled view of legitimacy, as opposed to a legal or sociological conception,[12] to construct a benchmark against which external trade policymaking in Europe can be evaluated. Legitimacy, in this view, occurs along two axes: the way the policy was made (procedural legitimacy) and the projected outcomes of policy (substantive legitimacy).[13] We must arrive at policies through democratic processes AND they must pursue just, equitable and fair objectives.

In an increasingly globalized world, a concern for the democratic quality of supra-state agencies and institutions has spawned a veritable cottage industry and many accept the existence of a so-called democratic deficit in global governance as conventional wisdom.[14] These developments are the consequence of the changing nature and locus of political authority under conditions of globalization. The emergence of global civil society can be understood, on one hand, to be a response to the changing nature of political authority under conditions of globalization and, on the other hand, as a conduit for global or regional democracy.[15]

As an agent of change, global civil society is engaged in a struggle for a global ethic; a struggle for a norm-governed system where democratic values infuse all levels of decision-making. So on one hand, the dissemination of global democratic norms begins from the ground up and is becoming more pervasive and influential as the moral authority of global civil society organizations is more widely accepted.

On the other hand, members of global civil society, including NGOs, can be viewed as a subject of global or regional democratic governance. According to Steven Bernstein, Cosmopolitan proponents of global democracy reason that "if individual autonomy, rights and consent are the basis of legitimate rule, then governance at any level can only be legitimated based on consent of individuals, public participation in and access to transparent decision-making processes that affect them, and accountability to them, with decision-makers perhaps even being subject to removal."[16] It follows then that procedural legitimacy beyond the state requires the formation of inclusive participatory mechanisms (at the sub-national, regional and supranational level) and public forums in which all citizens affected by the output of governance have equal opportunities to advance and debate their views. Indeed, proponents of cosmopolitan democracy envision the construction of an altogether

[12] For an in-depth analysis of the sociological and legal conceptions of legitimacy see Bernstein 2004.
[13] Max Weber (1968) draws this distinction between substantive and procedural legitimacy. Scharpf (1999) also makes a similar point arguing that legitimacy can either be won or lost on the input or output side of governance. For this point see Bernstein 2004.
[14] For the exception see Moravcsik 2004.
[15] On the emergence of global civil society see: Florini 2000; Boli and Thomas 1999; Lipschutz 2006; Germain and Kenny 2005; Matthews 1997; Shaw 1994. Mary Kaldor et. al (2005) also track the rise, ongoing activities and related issues of global civil society organizations in an annual yearbook.

[16] Bernstein 2004, 17.

new global polity, which consists of multiple sites of authority and decision-making designed to protect individual rights and enhance democratic decision-making. For instance, David Held[17] and his interlocutors[18] propose a democratic political order characterized by overlapping communities of fate where individuals enjoy multiple citizenships. They conceive of democratization as a "double-sided process" – involving the deepening of democracy within the state on the one hand and the extension of democratic forms and processes across territorial boundaries on the other.[19]

Global civil society is an essential feature of this model of procedural legitimacy since it constitutes the public sphere beyond the state and is thus a *subject* of post-national democratic governance. Building upon the insights of Jan Aart Scholte,[20] if the activities of NGOs improve the procedural legitimacy of external trade policymaking in the EU, we should observe the following implications:

1) Education

NGOs may engage in public education activities, disseminating information and generating public awareness of key trade-related issues. Fostering knowledgeable or informed citizens is viewed as key to democracy and public officials may facilitate the transfer of ideas and information between civil society organizations and citizens of the EU.

2) Public Debate and Deliberation

NGOs will be instrumental in generating and publicizing debate about substantive policy issues, normative ideas about what is fair and about the democratic quality of governance itself. Since "openings for dissent are as necessary to democracy as security consent"[21] policy debates will be widened to accommodate the expression of multiple views, even where they challenge prevailing policy orthodoxy.

3) Public Participation/Voice

NGOs will give a voice to otherwise marginalized groups in the political process. Improved access and new channels of participation will empower a broad range of stakeholders and, for civil society organizations participating directly in the policymaking process, will shift governance towards greater participatory democracy. EU officials will consult widely with all stakeholders who have a vested interest in the outcome of external trade negotiations.

4) Transparency

Decision-making will be more visible to EU citizens to allow for public scrutiny. We should see a gradual opening of access to documents and formal external (third party) policy evaluations or impact assessments will provide steady and reliable information. Procedures for consultation will also be made public. Preferential or differential access to policy-makers will be reduced or at least publicized. Also, mandatory and binding lobby disclosure rules may be implemented to improve greater stakeholder transparency.

[17] Held 1995.
[18] See for instance Archibugi 1993, 2000, 2004.
[19] Held et. al 1999, 450.
[20] The following hypotheses draw heavily from Scholte 2002, 293-295; Scholte 2004; 38-50.
[21] Scholte 2002, 294.

5) Public Accountability and Responsiveness

NGOs will push authorities to take greater public responsibility for their actions and policies. NGOs will publicize grievances in the media (otherwise known as naming and shaming) and these efforts may even be facilitated by EU policy-makers through access to information. Over time, formal mechanisms may be created to allow citizens to monitor and express concern through "auditors, ombudspersons, parliaments [and] courts" and/or to allow EU officials to respond to concerns.[22]

6) Redistribution

NGOs will work both through official democratic channels and informal networks to empower marginalized people by encouraging the redistribution of both economic and political resources. They will promote policies that encourage a fair distribution of resources in the global economy. They will generate public awareness of injustices through education. Finally, NGOs will launch independent projects designed to lessen worldwide inequality.

It is also necessary to look beyond the process through which policy is developed to question the projected outcomes or consequences of policy. Critical theorists have long considered global justice a key requirement of a legitimate political order.[23] The Neo-Gramscian "Approach,"[24] in particular, integrates questions of justice, social exclusion and moral credibility into their analyses of global politics. Global civil society, in this vein, may constitute the basis of an alternative world order. In other words, global civil society holds the latent potential to transform the prevailing structure of power relations and replace state-based political authority by instituting an alternative social order at local, regional and global levels through what Neo-Gramscians refer to as a "counter-hegemonic" movement.[25]

While "civil society has become the crucial battleground for recovering citizen control of public life,"[26] it is not certain that adding more NGOs and stirring will inevitably result in more just or equitable policies, at least in the near term. While NGOs advocate in favour of redistributive policies, there is no guarantee that they will influence policy choice in this direction. Even in the event of what Falk refers to as "normative renewal,"[27] there is a risk that improvements in post-national procedural legitimacy will not be matched by genuine substantive policy changes.[28] Indeed as David Kennedy asks, "Why are we limited to celebrating the expansion of participation in an emasculated policy process?"[29] This is precisely the pitfall this study aims to avoid.

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[22] Scholte 2004, 47.

[23] Gill 2000; Cox 1983, 1986; Murphy 2000. Louis Pauly (2002) makes a similar point, arguing that legitimacy requires social justice. However, for Pauly, this linkage precludes the transfer of political authority to the global level. Instead, states are limited to temporarily delegating authority while ultimately retaining the option of reasserting their regulatory autonomy in tough times.

[24]. For a sense of the range of Neo-Gramscian research see Rupert 1995, 2000; Rupert and Solomon 2006; Morton 2007; Beiler and Morton 2001; van Apeldoorn 2003; van der Pijl 1998; Overbeek 1993, 2003; Gill 1991a, 1991b, 2003; Cox 1987; Cox and Sinclair 1996.

[25] Cox 1999. Stephen Gill (2003) coins this bottom-up movement "transformative resistance", an altogether new form of political agency.

[26] Cox 1999, 27.

[27] Falk 1999, 46.

[28] Buchanan 2003.

[29] Kennedy 1999, 54.

Post-national substantive legitimacy is anchored to a global consciousness and the belief that social justice is not and should not be the sole responsibility of the state in a globalizing world. Under contemporary conditions, human lives are increasingly played out in the world as a single place; the life chances of individuals in developed, developing and least developed countries are interdependent and we all have universal obligations to one another. At a minimum, post-national substantive legitimacy requires an awareness of these changes and a concern for how our actions respond to and shape what is occurring elsewhere in the world.

At bottom, the precise criteria for social justice and equitable policies or post-national substantive legitimacy are part of a wider Cosmopolitan International Morality. The global application of Rawls' theory of distributive justice is therefore useful. In this respect, Thomas Pogge and Charles Beitz provide insight. They both reject the notion that states are analogous to individuals in domestic society in having rights of autonomy that insulate them from external moral judgment and political interference. Instead, both scholars advance a consequence-based[30] type of global distributive justice that applies to individuals (regardless of nationality) whose life chances and prospects are affected by a common institutional structure.[31] According to Beitz, "the requirements of justice apply to institutions and practices…in which social activity produces relative and absolute benefits and burdens that would not exist if the social activity did not take place."[32] Furthermore, "If evidence of global economic and political interconnectedness shows the existence of a scheme of social cooperation, we should not view national boundaries as having fundamental moral significance. Since boundaries are not co-extensive with the scope of social cooperation, they do not mark the limits of social obligations."[33]

To date, the global "rules of the game" in the multilateral trade regime have produced radical inequalities between people.[34] Nowhere is this more in evidence than in the asymmetries in the international trade regime.[35] It is widely accepted that the vast majority of welfare gains from successive rounds of multilateral trade negotiations have accrued to developed countries. For nearly 50 years, the agenda of trade negotiations has reflected the priorities of developed countries. In turn, developing countries shoulder a disproportionate range of obligations and responsibilities. The extension of trade rules into new areas, such as investment, services and intellectual property rights,

[30] Notably, the idea that the scope of distributive justice is coextensive with the impact of rules and institutions departs significantly from Rawls' understanding of distributive justice as fair reciprocity. According to Rawls, principles of distributive justice apply only to those who contributed to the creation of certain benefits. See Rawls 1971, 342-343. Pogge and Beitz aim to correct the exclusivity of Rawls' theory by placing emphasis on the degree to which individuals are affected by institutional rules and norms.

[31] This position can be distinguished from those who argue that principles of distributive justice apply to all on the basis of the equal moral status of human beings regardless of the extensity of social relations/cooperation or interdependence. For this view see Richards 1971, 1982. Both Beitz and Pogge reject this logic by arguing that Rawls' principles should not be applied internationally in the absence of international institutions since, under those conditions, it is only national institutions that produce benefits and burdens that affect their citizens.

[32] Beitz, 1979, 131.

[33] Beitz 1979, 51.

[34] Pogge 1989, 274.

[35] A diverse range of scholarship shares this sentiment. See Watkins and Fowler 2004; Stiglitz and Charlton 2005; Gallagher et al. 2005; McRae 2005; Lal Das 2003, 2006; Hoekman, Mattoo and English 2002; Matoo and Subramian 2004; Moore 2003. Also see "Mini-symposium on Developing Countries in the Doha Round" 2005.

has produced a knowledge or capacity deficit between developed and developing countries. Promises to redress these imbalances have remained unfulfilled.[36]

Pogge and Beitz argue that feasible, institutional alternatives that do not engender injustice and radical inequalities can be achieved through the global application of Rawls' difference principle.[37] In particular, Beitz argues that international rules and institutions should be reorganized to achieve a more just distribution of benefits and burdens (regardless of individuals' particular contributions) amongst affected individuals; global distributive justice requires that "social and economic inequalities are to be arranged so that they are…to the greatest benefit of the least advantaged." It is the globally least advantaged persons whose positions should be maximized.

Given this conception of substantive legitimacy, NGOs should be key advocates of redistributive trade policies. Indeed, if the involvement of NGOs improves the substantive legitimacy of EU external trade policymaking, I expect to find improved efforts to redress persistent economic inequalities between the north and south and widespread social injustices resulting from previous rounds of multilateral trade negotiations. In particular, if more just, equitable and fair external trade policies/proposals result from NGO efforts, we should see EU policymakers respond in the following ways:

1) EU policy-makers devise policy proposals that respond to social and environmental concerns and not just economic demands

2) EU policy-makers pursue policies aimed at redistributing the benefits associated with international trade from the North to the Global South

3) EU policy-makers pursue policies aimed at redistributing the burdens associated with international trade from the Global South to the North

4) EU policy-makers pursue Fair Trade[38] policy proposals

As I will demonstrate in the subsequent sections of this paper, EU policymakers did not pursue policies that ensured greater access to medicines, reduced disparities in access to medicines between the north and south, or which placed public health concerns over IPR protection, despite NGO involvement in the external trade policymaking process. Instead, I argue epistemes prevailed in the process.

Epistemes constitute the deepest level of the ideational world. They are comprised of shared, intersubjective or taken for granted causal and evaluative assumptions about how the world works. At bottom, they are invisible lenses that allow human beings to interpret and make sense of the world; people are rarely conscious of the fundamental assumptions that comprise the episteme

[36] Stiglitz and Charlton 2005, ch.2; Watkins and Fowler 2002.
[37] As Bernstein (2004, 18) notes, "Rawls explicitly rejects its international application in both *Theory* and *Law of Peoples*, instead arguing only for "a duty to assist other peoples living under unfavourable conditions that prevent them from having a just or decent political social regime". Indeed, for Rawls (1971, 114-118 and 333-342), natural duties are the only international moral requirements. However, Pogge (1989, 276) argues obligations of global distributive justice arise because "a global institutional scheme is imposed by all of us on each of us".
[38] LeClair 2003; Watkins and Fowler 2002.

except at critical junctures.[39] They are so powerful precisely because they are generally taken for granted and not amenable to scrutiny as a whole. Essentially, epistemes help people categorize, simplify and systematize what they experience in the world.

Epistemes are embedded in a common discourse through which people communicate about the world and thus define the range of problems that can be addressed. According to Adler and Bernstein, "Episteme thus refers to the "bubble" within which people happen to live, the way people construe their reality, their basic understandings of the causes of things, their normative beliefs, and their identity, the understanding of self in terms of others."[40] Notably, epistemes are numerous and permeable; the predominant episteme is just one among several possible sets of lenses through which to view the world.

Epistemes are powerful because they dispose human beings to behave in particular ways and they delineate the limits of the possible; they contain "background knowledge" or boundaries within which people reason and make choices. These boundaries may consist of "widely held accepted norms, consensual scientific knowledge, ideological beliefs deeply accepted by the collective, and so on."[41] Essentially, epistemes structure which actions and practices are conceivable and which are unimaginable.[42] The shift from GATT to WTO served to institutionalize or further entrench a *legal/liberal* episteme and this ultimately has implications for external trade policy governance in the EU.

Finally, epistemes empower technocrats and experts relative to other actors including global capital/business; as the episteme gains resonance these actors gain power (functional authority). Their work serves to maintain and reinforce dominant and largely universal norms, intersubjective ideas, rules of appropriate behaviour, consensual scientific knowledge and ideological beliefs. According to Adler and Bernstein, experts and technocrats gain functional authority under three conditions:

1) where they are required to make authoritative interpretations of the rules;

2) where they are required to develop standards in technical areas or;

3) through specialized cause-effect knowledge where their [policy] prescriptions gain legitimacy as focal points for cooperation, or the bases for new rules.[43]

Experts and technocrats are themselves the product of the dominant episteme and they work to co-opt and absorb forces of global civil society who resist or reject the prevailing episteme. On the other hand, those who cannot be co-opted may be marginalized and their work delegitimized.

In the following pages, I argue that EU policymakers responded positively to NGO demands for a voice and a role in external trade policymaking. In an effort to reproduce and legitimize the

[39] Kornprobst 2003.
[40] Adler and Bernstein 2004, 4.
[41] Adler and Bernstein 2004, 12.
[42] Adler and Bernstein 2004, 4.
[43] Adler and Bernstein 2004, 14.

legal/liberal episteme, steps were taken to make policymaking more transparent, accountable and open to participation by a wider range of both economic and non-economic actors. New opportunities for access and participation enabled actors who accepted the main tenets of the legal/liberal episteme to serve as interlocutors in the policymaking process; where discussions concerned the broad trajectory of policy, these actors played the role of educators and agenda setters. However, where policy discussions concerned the nuts and bolts of trade agreements and/or highly technical aspects of trade negotiations, policymakers "pulled away" from broadly participatory processes. Because technocrats and experts possess an authoritative claim on knowledge, the more technical (as opposed to political) the issue, the more functional power pooled in their hands rather than in those of corporate actors or NGOs. Political compromises were only struck when they were necessary to further the core goals of the episteme.

This pattern of empowerment precluded the possibility of introducing the policies advanced by NGOs because they were inconsistent with the requirements of the prevailing episteme and therefore, largely incomprehensible as policy solutions to decision-makers. Thus, the legal/liberal episteme conflicted with NGO attempts to move external trade policies in a more sustainable and just direction and thereby stunted the realization of moral or more substantively legitimate external trade policy governance. Although their involvement may bring improvements in procedural legitimacy through education, by giving voice to broader social concerns and generating public awareness and debate, the precise role of NGOs in bringing about more substantively legitimate (just, fair or equitable) policies is more promissory than actual despite improvements in participation and access.

III. Formulating the Doha Declaration: NGOs bring the *Access* Campaign to the EU

The shift from GATT to the WTO served to entrench a legal/liberal episteme in the international trade regime. Since epistemes are the lenses through which people view the world, the legal/liberal episteme defines, for WTO members, which actions and policy options are conceivable and which are unimaginable. At the core of the liberal dimension of the episteme is the belief that free trade and open markets are instruments for development and economic growth. The legal dimension of the episteme is the rule of law counterpart to these free market principles. Legal constraints are necessary to increase the legitimacy of the newly created WTO and to insulate trade policy and trade negotiations from political or regulatory interference with the free functioning of the market. The 1994 Agreement on Trade-Related Intellectual Property Rights (TRIPS) ushered in fundamental normative and substantive changes in the global intellectual property rights (IPR) regime. For the first time, stringent intellectual property norms were codified, legalized and linked to the international trade regime.[44]

By situating IPR inside the legal/liberal episteme, WTO members defined, perhaps unconsciously, the "limits of the possible" in subsequent TRIPS trade negotiations. The substantive disciplines contained in the WTO Agreements delineate the appropriate trajectory of new international trade rules. As such, they work to constrain the range of policy options considered appropriate by policymakers in the EU. These ideational and legal constraints inevitably impact and structure dialogue and consultation between NGOs and policymakers in the EU.

[44] For further discussion of the TRIPS Agreement see Sell 2003; Correa 2006; Cottier 2005; Matthews 2002.

In the run up to the TRIPS Agreement in 1994, the EU adopted a hard-line market-oriented approach to IPR protection. IP-based industry, represented by the Union of Industrial and Employers' Confederations of Europe (UNICE), was the EU's key partner on this issue. However, beginning in 1998, the Access to Medicines Campaign spread to Europe and dramatically changed the dynamics between EU technocrats and civil society. NGOs became key interlocutors with EU officials and, through a multi-pronged strategy, sought to compel EU decision-makers to initiate a Ministerial Declaration that would clarify TRIPS provisions on public health and guarantee governments' rights to put public health concerns above IPR protection.

In Europe and elsewhere, NGOs launched a massive media blitz designed to generate public awareness about the link between IPR enforcement and public health. They issued countless press releases and held numerous demonstrations to publicize grievances against EU policymakers and to inform the public about the EU's practice of cracking down on poor Africans dying of HIV/AIDs as in the case of South Africa.[45] By late 1999, EU policymakers realized that they would ignore the Access Campaign at their peril. Indeed, it became clear that progress in the context of a new round of Multilateral Trade Negotiations could not proceed until the issue was addressed. In partial response, EU policymakers created access points and opened up forums for formal and informal consultations with CSOs working on a range of issues including public health. These new mechanisms for consultation constituted an explicit attempt to legitimize the international trade regime, to make the prevailing legal/liberal episteme more sustainable and to deflect public scrutiny away from the substantive impact of new rules.

Members of the Access Campaign were invited to participate in a series of structured Civil Society Dialogues, beginning in 2001.[46] In part, this initiative was designed to improve transparency and public accountability of EU decision-making, especially as it pertained to the impact of TRIPS enforcement on public health. European Commission officials supplemented the input generated during structured, public dialogues with more informal, weekly one-on-one meetings with a select number of NGOs such as MSF and Oxfam in the period preceding the Doha Declaration.

In addition to direct consultations, members of the Access Campaign developed and distributed concrete proposals for action to EU policymakers. For example, prior to the June 2001 TRIPS Council Meeting, MSF drafted a list of recommendations for discussion and submitted it to the European Commission.[47] Members of the Access Campaign also made several submissions and directly lobbied members of the European Parliament.[48] Although the European Parliament (EP) lacked any formal decision-making powers, the Commission consulted regularly with International Trade (INTA) Committee during this period. The EP also passed a series of resolutions that reflect the priorities of the Access Campaign.[49]

Clearly, NGO activity has not been limited to media campaigns. They have also been actively involved in formulating policy positions and offering guidance on substantive issues. The

[45] See for instance Oxfam 2001.
[46] For in-depth and comprehensive overviews of the CSD see WWF 2002 and Slob and Smakman 2006.
[47] MSF 2001a.
[48] See for example MSF 2001b.
[49] See for example European Parliament 2001a. For more recent resolutions along these lines see European Parliament 2006a, 2006b, 2007.

consensus amongst policymakers in the EU is members of the Access Campaign were instrumental in generating awareness about the public health implications of the TRIPS Agreement. NGOs provided critical expertise and experience that EU policymakers would otherwise not have accessed.[50] In their absence, EU policymakers claim they would have no idea about the significance of the AIDs crisis in the developing world or its link to IPR enforcement.[51]

From this brief overview, it is clear that NGOs became key interlocutors in the European Union in the period preceding the Doha Declaration. Their work in the media was instrumental in generating public debate and disseminating information about the link between IPR protection and the AIDS crisis in Africa. While the Pharma[52] industry continued to enjoy its status as "social partner" through its membership in UNICE, its views were counterbalanced by the participation of NGOs in the external trade policymaking process. NGOs launched a sustained effort to reorient the EU's approach to IPR enforcement in developing countries. In this way, they worked to give a voice to developing countries and the world's poorest people whose interests had otherwise been marginalized in TRIPS negotiations. They enjoyed dramatically enhanced access and participatory conditions and their involvement improved the procedural legitimacy of external trade policymaking in the EU. By providing education and generating awareness about the issue, NGOs played a decisive role in shaping and informing the debate over the impact of the TRIPS Agreement on Access to Medicines.

The EU's position on TRIPS and public health shifted significantly between 1998 and 2001 and parallels, in many respects, the concerns of the Access Campaign. By dropping its objection to the use of compulsory licensing, the EU distanced itself from the South African case and endorsed a broad US commitment made at the Seattle Ministerial Meeting to adjust external trade policy to support access to HIV/AIDs drugs in Africa. In February 2001, the EU made a further and more explicit commitment to alter its external trade and development policies to improve access to essential medicines in developing countries. The Programme for Action to Confront HIV/AIDS, Malaria and Tuberculosis commits the EU to the following objectives: to increase the impact of existing interventions, make key pharmaceuticals more affordable, and support research and development of specific global public goods to confront these diseases.[53] The EU also became an advocate for a global tiered pricing system for pharmaceuticals.[54]

At the international level, EU efforts ensured that the public health implications of IPR protection would figure prominently on the international trade agenda. The submission by the EC to the TRIPS Council in June 2001 signaled a change in the EU's approach to IPR protection that reflects

[50] Sabine Weyand. DG Trade, Member of Pascal Lamy's Cabinet, Responsible for Relations with European Parliament; Social Partners and NGOs; Transport; Energy; Sustainable Development; Employment and Social Affairs; Environment; European and Social Committee (ESC) until November 2004. Interview by Author.
[51] Lanoszka 2003, 192.
[52] This is a common reference to major research-based pharmaceutical enterprises operating on a global scale. It should be distinguished from PhRMA, a US-based pharmaceutical industry lobby organization.
[53] European Communities 2001a.
[54] The Programme For Action states, "The European Community will work towards the introduction of tiered pricing as the norm for the poorest developing countries, while seeking to prevent re-importation to the EU market." See European Communities 2001a Section 3.2.1. For further details on steps taken by the EC to avoid trade diversion, the practice of diverting discounted products intended for poor countries back into high priced markets, see European Communities 2003.

the goals of the Access Campaign.[55] In particular, the EU explicitly acknowledged the freedom of all WTO members to decide the circumstances under which to grant compulsory licenses and expressed willingness to negotiate a solution to Article 31(f). It emphasized that Articles 7("Objectives") and 8 ("Principles") of the TRIPS Agreement already allow the right of all members to take measures to protect public health. The EU did maintain an industry-oriented, hard-line approach to Article 30 exceptions and data protection. However, the significance of this would not be immediately clear. During a special informal meeting of the TRIPS Council on 25 July 2001, the idea of crafting a specific Doha Declaration was launched. The EU played the role of "honest broker,"[56] acting as a mediator between developing countries on one hand and the US, Australia, Canada, Switzerland, and Japan on the other.[57] Overall, the EU supported an interpretation of TRIPS in a manner that supports public health interests and sought to encourage a compromise solution between North and South. In fact, Pascal Lamy, DG Trade Commissioner at the time, is credited with providing decisive leadership in getting the Doha Declaration on the TRIPS Agreement and Public Health passed by the WTO Ministerial Council.

The Doha Declaration on the TRIPS Agreement and Public Health, adopted by the WTO Ministerial Conference on 14 November 2001, is widely cited as a victory for the Access campaign.[58] This document explicitly recognizes the gravity of the public health problems afflicting developing and least developed countries and acknowledges that stringent IPR protection may have a negative impact on access to affordable medicines. The essence of the Declaration is contained in Article 4 of the Declaration:

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

This paragraph affirms that provisions in the TRIPS Agreement should be interpreted in light of the principles and objectives of the Agreement contained in Articles 7 and 8 respectively. In the event of a dispute, these articles will be used by panels and the Appellate Body "as primary interpretation tools when determining the TRIPS-compatibility of measures taken by a Member in view of protecting public health."[59]

The Declaration (Para. 5b) clarifies that all WTO member states have the right to grant compulsory licenses under any conditions they deem appropriate. Members also have the right to determine what constitutes a national emergency or other circumstances of extreme urgency (Para. 5c). This principle is in stark contrast to the United States' preferred outcome which would have established

[55] Council for TRIPS 2001a.
[56] Abbott (2002, 486) notes that the EU backtracked temporarily from its 'pro-health' positioning in the pre-Doha talks when it submitted a non-paper draft declaration that reflected the US/like-minded group position. The Commission delegation noted that the paper had not been approved by member states. It subsequently withdrew the paper and repositioned itself in the middle ground of TRIPS: Access to medicines negotiations.
[57] For a thorough overview of intergovernmental negotiations leading up to the Doha Declaration see Abbott 2002b.
[58] WTO 2001.
[59] Van Eeckhaute 2002, 14.

an exhaustive list of "qualifying" diseases.[60] Furthermore, the Declaration reconfirms Members' rights to establish their own regime for exhaustion of intellectual property rights thereby leaving the door open for parallel importation without challenge (Para. 5d). Finally, Paragraph 7 encourages developed countries to transfer technology to least-developed country members and reiterates the right of least-developed countries to opt for an extension of the transitional period of the TRIPS Agreement until 2016. What the Doha Declaration leaves unresolved is the problem created by TRIPS Article 31(f) for countries without domestic manufacturing capacity or insufficient market demand. Instead, Paragraph 6 of the Doha Declaration recognizes this problem and commits the TRIPS Council to finding "an expeditious solution to this problem and to report to the General Council before the end of 2002."[61]

If the analysis were to stop here, as much of the existing literature that celebrates the achievements of the NGO-led Access Campaign does, we could draw very optimistic conclusions about the ability of NGOs to influence EU policymakers and to affect policy outcomes by establishing and strengthening global norms to the point that even great powers cannot ignore them.[62] There are certainly clear correlations between the demands made by members of the Access Campaign and the policy line pursued by EU policymakers in Doha. In the immediate aftermath, the outcomes achieved in the Doha Declaration were celebrated by activists and policymakers alike as going great distances to redress persistent inequalities in international trade rules, ensuring individual members' rights to protect public health and building fairness into the global IPR regime. From this account, it would appear that NGOs were instrumental in bringing about more substantively legitimate external trade policies in Europe. If so, then the Cosmopolitan explanation succeeds, at least in this "easy test," in accounting for the role of NGOs in the EU's external trade policymaking process. However, the extent to which the EU's position on public health norms actually underwent substantive and normative change is questionable. In fact, it appears the early successes attributed to the Access Campaign were exaggerated. [63]

With the exception of the extension of the transitory period for least developed countries, the Doha Declaration served to clarify already existing flexibilities contained in the TRIPS Agreement.[64] Moreover, the issue of access to medicines was a deal breaker at the Ministerial Conference in Qatar. Developing countries had linked it to a range of issues including textiles, investment, and agriculture. According to Haochen Sun, "[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."[65] Rather than constituting a major normative or substantive change in the global IPR regime, the Doha Declaration was merely a political compromise designed to quiet developing countries and NGOs so progress could be made in other, arguably more crucial, areas of multilateral trade negotiations. A closer look at Paragraph 6 of the Doha Declaration and subsequent developments since a solution was reached, reveal that early optimism regarding the significance of the Doha Declaration on one hand, and the EU's "shift" in position on the other were overstated. In many respects, the EU has fallen back to its hard-line

[60] Council for TRIPS 2001b.
[61] For further discussion on the accomplishments contained in the Doha Declaration see Abbott 2002a; Correa 2002.
[62] See Sell and Prakash 2004, 167.
[63] Drezner (2005) raises similar doubt with respect to the United States' position on TRIPS and Public Health.
[64] Notably, most African countries have already brought national patent legislation into line with the TRIPS Agreement.
[65] Quoted in Drezner 2005, 23. Also see De Jonquieres 2001.

market-oriented approach to IPR protection, which calls into question the extent to which public health norms disseminated by the Access Campaign actually took hold.

IV. August 30th Agreement and the Protocol of TRIPS Amendment Concerning Article 31bis: EU Technocrats Build Deliberate Limitations and Bureaucratic Complications into the Solution

Between November 2002 and December 2005, the task of solving the Paragraph 6 problem shifted the TRIPS and Public Health matter from a political issue to a highly technical one. As a consequence and despite newly created mechanisms for access and participation for CSOs, policy discussions in the EU "pulled away" from the deliberative or a broadly participatory process. Functional power pooled in the hands of European technocrats working in DG Trade and policy outcomes did not reflect the preferences of NGOs. Instead, European technocrats were the architects of a highly complex solution, the so-called August 30th Solution, fraught with bureaucratic red-tape. The European technocrats crafted a solution to Paragraph 6 that they never intended to function in practice. Instead, it is hoped that the threat of its use and indeed threat of competition from generic firms will compel patent holders to sell drugs at lower costs. The effectiveness of this solution therefore depends on the market and competition between firms working to shift patent holder strategies from a "high cost, low margin" approach to a "low-cost, high margin" approach. European technocrats were staunch advocates of the expeditious legalization of the solution, however imperfect, and on 6 December 2005 the General Council accepted it as a permanent amendment to the TRIPS Agreement. The EC subsequently passed a Regulation[66] on 17 May 2006 implementing and giving "direct effect" to WTO General Council Decision of 30 August 2003. Ultimately, the work of EU technocrats is grounded in the belief that market forces will provide equitably priced medicines and ensure research and development for infectious diseases in developing countries – a position that is diametrically opposed to the demands of NGOs working as part of the Access Campaign in Europe.

The importance of solving the Paragraph 6 problem was acute since the supply of low-cost, generic medicines would dry up as developing countries brought their patent legislation into line with their TRIPS obligations on 1 January 2005.[67] Only a few developing countries have pharmaceutical manufacturing capacity but prior to the end of the patent system moratorium for countries like India, developing countries were free to import generic copies of life saving drugs such as first line antiretroviral treatments (ARVs).[68] In fact by 2005, 70% of the HIV/AIDS treatments provided by MSF were imported from generic firms in India.[69] All new products produced after the 2005 deadline would be subject to full patent protection but generic versions of products produced between 1995 and 2005 would still be available provided the generic producer pays royalties to the patent holder.[70]

Prior to the adoption of the Doha Declaration, developing countries were already acutely aware of the problem caused by Article 31(f).[71] They proposed using TRIPS Article 30 as a basis for a

[66] European Communities 2006.
[67] Ismail 2003.
[68] The HIV/AIDS crisis serves as a magnifying glass for the wider problem of access to medicines.
[69] MSF 2005b.
[70] Haakonsson and Richey 2007, 79. It is estimated that between 4200 and 12000 patent applications had accumulated in India's "Mailbox" between 1995 and 2005.
[71] Council on TRIPS 2001c.

solution to the problem. This solution would allow Members to "give effect" to compulsory licenses issued by other members, and to export pursuant to those licenses. This solution required the development of an authoritative interpretation that would allow Members to "use the Article 30 exception provision to authorize production for export "to address public health needs in importing Members."[72] However, the EU and the United States roundly rejected this proposal and sought to resolve the issue at a later date. Unfortunately, momentum and political will declined significantly after Doha and the TRIPS Council was unable to find a "simple and expeditious solution to this problem…before the end of 2002."[73]

By July 2002, the TRIPS Council had received a number of communications on a solution to the Paragraph 6 problem.[74] The four main proposed solutions indicated that a consensus would be difficult to reach. First, developing countries maintained their preference for a solution under Article 30 that would provide for a specific exception for exports by means of an authoritative interpretation. Since this solution would result in a broad and general exception in WTO Members' patent laws, it was widely viewed as the most "administratively simple, workable and economically viable."[75] The Access Campaign and the World Health Organization were also staunch advocates of this proposal.[76]

NGOs preferred this solution because the patent holder would receive remuneration in the country where the pharmaceutical product is consumed thereby avoiding double compensation. It also permits the export of products to countries that have not filed or granted patents. It encourages exports from the widest number of countries and, perhaps most significantly, this solution does not place the power to determine the appropriate conditions for granting a compulsory license in the hands of the exporting country.[77]

In June 2002, the Africa Group proposed a second option, a moratorium whereby WTO members would agree not to bring disputes against countries that export some medicines to countries in need.[78] The United States expressed its preference for a temporary moratorium a month later.[79] However, any solution, according to the United States, should be limited to epidemics explicitly referenced in the Doha Declaration: HIV/AIDS, Malaria, Tuberculosis.[80] The possibility of "waiving" certain WTO Members from specific obligations under the TRIPS and thereby making exports to select countries "non-judiciable," was also suggested by the United States' as an interim

[72] Abbott and Reichman 2007, 6.
[73] WTO 2001.
[74] These communications were by the African Group (Council on TRIPS 2002c), the EC and their Member States (Council on TRIPS 2002a, b), United Arab Emirates (Council on TRIPS 2002d), Brazil, on behalf of Bolivia, Brazil, Cuba, China, the Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela (Council on TRIPS 2002e), and the US (Council on TRIPS 2002f, g).
[75] 't Hoen 2003, 59. For the same reason, Pharma vigorously opposed this solution.
[76] See for instance 'Joint Statement' 2002a, b; Oxfam 2002.
[77] These points were conveyed in a letter to the TRIPS Council by six leading members of the Access Campaign. See MSF et al. 2002.
[78] Council on TRIPS 2002c.
[79] Council on TRIPS 2002g.
[80] Ismail 2003, 399. Notably, the United States acted upon its offer to grant moratoriums to developing countries following the TRIPS Council's inability to find a solution to Paragraph 6 in December 2002. USTR Press Release 2002.

solution until consensus on Paragraph 6 could be attained.[81] Nonetheless, both the waiver and moratorium options are temporary solutions that suffer from an inherent lack of legal stability and predictability - key values underpinning the international trade regime – and were therefore viewed as unsustainable.[82]

A third option involved carving out an exception to Article 31 of the TRIPS Agreement through an amendment. The African Group and its partners suggested that an amendment should simply delete the paragraph in Article 31(f) that limits the production of products "predominantly for the domestic market." Others proposed the introduction of a limited exception that would apply only under certain circumstances "for exports of products needed to combat serious public health problems and produced under compulsory licenses."[83] In the event of an amendment to Article 31(f), compulsory licenses would be granted on a case by case basis. Therefore, this is a much more restrictive solution than the one proposed under Article 30. Nonetheless, this solution would provide the basis for the Decision of the General Council of the WTO on August 30 2003.[84]

Initially, the EU resumed its role as honest-broker in international negotiations. In its communications to the TRIPS Council in March 2002, the EU presented both the Articles 30 and 31 solutions as viable options.[85] In the meantime, the EU struggled internally to forge a common position. Due to pressure from its sizeable pharmaceutical industry, Germany maintained a position most in line with the United States while many other Members sought a much broader solution under Article 30. The UK Commission on Intellectual Property Rights also implicitly endorsed this solution by emphasizing the importance of economies of scale for generic producers.[86]

There was also considerable political wrangling between different institutional arms of the EU. DG Internal Market and the patents working group of the Council of Ministers both sought restrictive solutions that would not lower intellectual property protection standards. By contrast, DG Development and the European Parliament stood squarely behind a solution based in TRIPS Article 30.[87] In fact, on 23 October 2002, the European Parliament passed Amendment 196 to the EU Directive 2001/83/EC relating to medicinal products for human use officially endorsing an Article 30-based solution. Article 10 Para 4 states:

> Manufacturing shall be allowed if the medicinal product is intended for export to a third country that has issued a compulsory license for that product, or where a patent is not in force and if there is a request to that effect of the competent public health authorities of that third country.

[81] Bourgeois and Burns 2002; Vandoren and van Eeckhaute 2003. A waiver could be granted under WTO Article IX.3-4 which states: In exceptional circumstances, the Ministerial Conference may decide to waive an obligation imposed on a Member by this Agreement or any of the Multilateral Trade Agreements, provided that any such decision shall be taken by three fourths of the Members unless otherwise provided for in this paragraph
[82] Matthews 2004, 85.
[83] Council on TRIPS 2002a.
[84] WTO 2003a.
[85] Council on TRIPS 2002b.
[86] UK Commission on Intellectual Property Rights 2002, Chap. 2-Health, 44-48.
[87] Desk officer working on international aspects of intellectual property rights, in particular in regards to access to health. DG Trade, Unit H2: New Technologies, Intellectual Property and Public Procurement. Interview by author.

This amendment is widely considered by NGOs to contain an "ideal solution" or blueprint for solving the Paragraph 6 problem but it has since been rejected.

By June 2002, the EC and its Member States had already positioned themselves squarely behind an Article 31 amendment and were preoccupied with clarifying modalities.[88] Despite considerable intergovernmental wrangling over a range of issues including the scope of diseases covered by the amendment, whether the exception should be limited to least-developed countries, which countries qualify as exporters of low-cost essential medicines, and the need for additional safeguards, the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS and Public Health was adopted on 30 August 2003.[89]

Momentum for meeting with CSOs endured throughout 2002 and 2003. The Civil Society Dialogue met three times in 2002 and four times in 2003. In each instance, the lead commission participant was the Head of the Unit working on IP, Paul Vandoren. However, by early 2003, the quality of discussion, especially as it pertained to a Paragraph 6 solution, declined significantly. As the policy debate centered on issues that required a good deal of legal and technical know-how, discussions were "pulled back" from the burgeoning participatory process. Even DG Trade's most avid and trusted NGO partners were effectively relegated to the status of "passive receivers" of information. According to actors on both sides of the debate, Civil Society Dialogues became one-sided "de-briefing sessions" where Commission officials inform members of civil society about their activities at the TRIPS Council and their position/work on modalities for implementing a solution under Article 31(f).[90] The floor was open for participants to ask one or two questions, but unlike the pre-Doha Declaration period, there was no longer any opportunity for meaningful debate.[91] NGOs report that the sessions ended before they could advance their own point of view on the issues.[92] The intensity and quality of input were reportedly diminished during one-on-one meetings between MSF, Oxfam and Commission officials. Moreover, NGO activism began to stagnate during this period. As the issues became more complex, and dialogue less likely, NGOs had difficulty maintaining interest amongst their membership.[93]

A. *August 30 Decision*

The August 30 Decision[94] was an interim solution in the form of a waiver of Article 31(f), agreed to before the Cancun Ministerial Meeting in September 2003.[95] It effectively allows the import of generic pharmaceuticals under compulsory license on a case by case basis, provided that certain conditions are met. Despite attempts by the international research-based pharmaceutical industry

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[88] Council for TRIPS 2002c.

[89] For a detailed overview of the intergovernmental negotiations leading up to the August 30 Decision and a close examination of US efforts to block an expeditious and efficient solution to the paragraph 6 problem see Baker 2003, Section 2.3; Matthews 2004; Abbott 2005. Matthews (2002) also conducts a thorough comparison of US and EU negotiating strategies during this period.

[90] Desk officer working on international aspects of intellectual property rights, in particular in regard to access to health. DG Trade, Unit H2: New Technologies, Intellectual Property and Public Procurement. Interview by author.; Seco Gerard. MSF Access Campaign: EU Liaison Officer. Interview by author.

[91] Summaries of the Civil Society Dialogues for this period are available at http://trade-info.cec.eu.int/civilsoc/meetlist.cfm?pastyear=2003 and http://trade-info.cec.eu.int/civilsoc/meetlist.cfm?pastyear=2002

[92] Louis Belanger. OXFAM International: EU Advocacy and Media Officer. Interview by author.

[93] Seco Gerard. MSF Access Campaign: EU Liaison Officer. Interview by author.

[94] Previously referred to as the "Motto Text".

[95] For a detailed description and analysis of the different aspects of the decision see Baker 2003.

and the United States,[96] the Decision does not limit the scope of diseases[97] nor does it restrict usage to least-developed or Sub-Saharan African countries.[98] The Decision requires that importing countries (excluding least-developed countries[99]) notify the TRIPS Council website of their general intent to make use of the system. Countries may also make a declaration of their intention not to use the system or to use it in a limited way.[100] The importing member must also provide the names of the pharmaceutical products and the quantities it expects to import, and confirm that it has insufficient or no manufacturing capacity in the sector to produce the product in question.[101] If the drug is patented in the importing country, it must grant a compulsory license in accordance with Article 31 TRIPS.[102]

Exporting WTO members must also issue a compulsory license but it must only be for the amount necessary to meet the needs of the importing Member as indicated in its notification to the TRIPS Council.[103] All of the product produced under the compulsory license must be exported to that member and be clearly identified as having been produced under this system through special labeling or markings, provided that such distinction is feasible and does not have a significant impact on price.[104] The exporting member must post quantities, destinations and distinguishing features of each product prior to shipment for export on a website and notify the TRIPS Council of its location.[105] The TRIPS Council must also be notified by the exporting member when a compulsory license is issued, "the name and address of the patent holder, the product(s) for which the license has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the license."[106] Finally, the Decision

[96] Ismail 2003, 398; Elliot and Denny 2002. At one point, in an effort to break deadlock, the European Union also recommended limited disease scope to a list 'approved' by the WHO.
[97] This move would have been inherently discriminatory since developed countries with manufacturing capacity do not face disease limitation on the grant of compulsory licenses.
[98] According to Paragraph 1(a) of the Decision, pharmaceutical product"means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the [Doha] Declaration." WTO 2003a. According to Abbott and Reichman 2007, this includes active ingredients, vaccines and diagnostic kits required for treatment of any disease. Paragraph 1 of the Doha Declaration does not limit the Declaration's applicability to specific diseases or medicines.
[99] Least-developed countries are exempt from this requirement since they are assumed to lack the manufacturing capacity to produce pharmaceuticals and are thus already eligible to use the system.
[100] Most OECD countries and all EU Member States including newly acceded countries have made such a declaration. This decision has been the subject of debate in light of the Avian flu virus. Abbott and Reichman 2006. See also the debate in the Civil Society Dialogue on 27 October, 2005 on this issue: http://trade-info.cec.eu.int/civilsoc/meetdetails.cfm?meet=11125
[101] WTO 2003a, Para. 2(a)(ii) and Annex: Assessment of Manufacturing Capacities in the Pharmaceutical Sector.
[102] Least Developed Countries are exempt from this requirement because they need not apply patent or data protection for pharmaceuticals until 2016. Least developed countries that had already introduced patent regimes, largely as a result of colonial administration of their legal systems, have the right to dis-apply existing patent protection for this period. Notably, TRIPS Article 31(b) contains a "fast-track" provision that states compulsory licenses issued for public non-commercial use and/or national emergency or circumstances of extreme urgency do not require notification or prior negotiations with the patent holder. Abbott and Reichman 2007, 13. Also see Vandoren and Van Eeckhaute 2003.
[103] Notably and despite Canada's claim to the contrary, TRIPS Article 31(b) or the "fast-track"option also applies to exporting members. Abbott and Reichman 2007, 13.
[104] WTO 2003a, Article 2(b)(ii).
[105] WTO 2003a, Article 2(b)(iii).
[106] WTO 2003a, Article 2(c).

requires that adequate remuneration be paid to the patent holder in the exporting country.[107] This provision ensures that remuneration required under TRIPS Article 31(h) is not paid twice.

The Decision was accompanied by the reading of the "General Council Chairperson's Statement"[108] It includes an extra statement of purpose intended to provide assurances to the United States in particular so that the Decision would not be abused[109] and products would not be diverted to third-country markets.[110] The statement provides for ad hoc reviews of determinations of insufficient manufacturing capacity. It also lists the 47 WTO members who had made statements of either complete or partial non-use of the Decision as importers.

Members of the Access Campaign immediately issued widespread and unequivocal denunciations of the August 30 Decision.[111] It is viewed as a flawed deal that is likely to make the access to essential medicines situation in developing countries far worse.[112] The system entails onerous administrative costs for developing countries with limited resources and it is considered too complicated to work in practice.[113] According to members of the Access Campaign who lobbied EU technocrats, the burden of proof on developing countries to establish that they lack sufficient manufacturing capacity and the possibility of review by the TRIPS Council will compromise their willingness to make use of the system. This provision raises the specter of costly legal battles and/or trade retaliation in other areas for countries who apply to use the system. The precise meaning of "insufficient capacity" is unclear and therefore subject to dispute. NGOs believe any solution to Paragraph 6 must include situations where it is economically inefficient to produce a particular product; that is, where meaningful economies of scale are lacking. However, in the absence of an expansive definition of "insufficient capacity" it remains unclear whether this situation qualifies. NGOs also take issue with the fact that potential importers under this system are entirely dependent upon government decisions in exporting countries.[114]

According to the Access campaign, an energetic market in developing countries for generic medicines is essential to combat AIDS and other public health problems. However, the Decision also makes it difficult for generic producers to establish viable economies of scale that will drive the price of essential medicines down. There is concern that in the absence of competition, Indian and

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[107] "Taking into account the economic value to the importing Member of the use that has been authorised in the exporting member" WTO 2003a, Article 3.
[108] WTO 2003b. For further discussion on the practical significance of the Chairperson's statement see Baker 2003; Abbott and Reichman 2006, 17-18.
[109] "Members recognize that the system established should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial objectives." WTO 2003b.
[110] WTO 2003b.
[111] Cptech has posted press releases, letters and position papers from various actors on this issue during the 2002-2005 period. See http://www.cptech.org/ip/wto/p6/
[112] Louis Belanger. OXFAM International: EU Advocacy and Media Officer. Interview by Author.
[113] For a detailed assessment of the administrative aspects of the Decision see Baker 2003; Abbott and Reichman 2007; Matthews 2004. To date, only Rwanda has notified the TRIPS Council of its intent to use the system by importing 260, 000 packs of 'Apo-TriAvir', a combination HIV/AIDS drug from Canada. Notably, Apotex, the generic firm that won the tender to manufacture and export the drug to Rwanda, says it will never participate in such an arrangement again because the procedure was so cumbersome and consumed so many company resources. For further details see ICTSD 2007a; Gandhi 2008.
[114] Stop AIDS Campaign 2005, 24.

Brazilian generic industries can be predatory in the pricing practices.[115] The system does not allow for international tendering and the requirement for double licensing (in both the importing and exporting countries) adds an unnecessary layer of bureaucracy and uncertainty for generic producers. Because they may only produce products for export on a case-by-case, license by license basis, prospective generic producers may be deterred from building up capacity for export on "speculation." NGOs are also concerned that the requirement for distinctive labeling to prevent trade diversion and the payment of remuneration in wealthy OECD countries[116] will drive generic prices upwards.

The generic industry has echoed many of these concerns. In particular, the European Generics Association considers the system so constraining and legally risky that it will not be able to make use of it. In a comment on the European Commission's initiative to introduce a Regulation implementing the August 30 Decision, the EGA stated, "the procedures are complicated, the terms under which new procedures must operate are very restrictive, and the various measures proposed are ambiguous."[117] The comment went on to doubt the extent to which the Decision could function in practice to improve access to medicines in other countries.

The Decision also failed to meet the expectations of the international research-based industry. It was especially frustrated by the decision not to include limits on the scope of diseases but was appeased by the Chairperson's statement and the declarations of non-use by a wide range of countries.

Once the EU had explicitly endorsed a solution based in Article 31(f), there was no possibility of compromise with NGOs working with the Access Campaign who denounced the Decision wholesale. In part, this explains the decline in the quality of dialogue between late 2002 and August 2003. The diminishing quality of consultations between EU technocrats and NGOs in this period is also due to a fundamental disagreement over the appropriate solution to high prices for essential medicines in developing countries. As discussed at some length above, the Access Campaign attributes the high price of medicines to stringent IPR protection and therefore looked for greater flexibility in IPR enforcement vis-à-vis TRIPS Article 30. Commission officials cite a range of other problems including the failure of public policy, lack of health infrastructure and distribution channels and do not view compulsory licenses as a viable or sustainable solution to the access problem in developing countries. Instead, the European Commission favours voluntary (market-based) mechanisms.

EU technocrats forged the August 30 decision with the intent to maintain IPR protection and to provide legal certainty for the pharmaceutical industry; two qualities that were lacking in an Article 30 solution. EU Commission officials were the architects of many of the most cumbersome and bureaucratic elements of the August 30 decision. They built deliberate limitations and complications into the system. Although the reading of the Chairperson's statement was meant to appease the United States and allow it to sign on to a solution while saving face in light of Pharma demands, it effectively wrapped an already complicated solution in even more red tape. European technocrats do not expect an Article 31 solution to function in practice. The "threat" of compulsory

[115] Jennifer Brant. Trade Policy Advisor to Oxfam America. Interview by author.
[116] According to Baker (2003, 25) the entire issue of calculating remuneration in exporting countries is a Pandora's box.
[117] EGA 2005, 2.

licenses, arising from an amendment to Article 31, should lead to spontaneous price reductions as patent holders issue voluntary licenses and/or sign on to a voluntary global tiered pricing scheme; both options are considered to be more "sustainable" solutions to high priced medicines. Therefore, all NGO arguments regarding the cumbersome and complicated nature of the solution are moot from the point of view of the Commission. Once a decision had been made to support an Article 31 solution to the Paragraph 6 problem, Commission officials shifted attention to highly technical matters including the precise form or limits on compulsory licensing, tiered pricing and related "safeguards against the diversion of low-priced pharmaceuticals …and price erosion in the markets of developed countries."[118]

B. Protocol of TRIPS Amendment Concerning Article 31bis

After August 2003, policy discussions focused on finding a permanent solution to the Paragraph 6 problem and the issue became even more complex and technical. As a result, additional functional power pooled in the hands of EU technocrats who sought to make use of their carefully crafted August 30 Decision as an authoritative basis for a new and permanent rule on compulsory licensing in countries with no manufacturing capacity. The quality of engagement between EU technocrats and NGOs working with the Access Campaign degenerated further. Where they once served as key interlocutors to the Access to Medicines debate in the EU's external trade policymaking process, NGOs were effectively sidelined at the implementation and policymaking stage. Their participation was once celebrated and considered vital to making progress on the issue. However, in the post-August 2003 policymaking environment, EU technocrats questioned whether public health advocates and NGOs even qualify as stakeholders. Only two formal Civil Society Dialogues were held between September 2003 and December 2005.[119] In previous years, the head of DG Unit H2: New Technologies, Intellectual Property and Public Procurement was the lead participant in dialogues with civil society. Following the August 30 Decision, low-level administrators from DG Trade Unit H2 attended the meetings in a "de-briefing" capacity. Regular informal contact was maintained with MSF but it is reported that these sessions were frustrating and unproductive in the absence of any possibility of compromise.

NGOs report difficulty in maintaining momentum and interest in their campaign. They were at a distinct disadvantage in the policymaking process because of the highly technical nature of policy discussions. It was difficult to develop sufficient technical and legal expertise amongst membership to engage in substantive policy debates.[120] Therefore, members of the Access Campaign focused their efforts on more general public statements and position papers calling for developing countries to resist EU and US pressure to translate the August 30 Decision into a permanent TRIPS Amendment.[121] NGOs also targeted Members of the European Parliament calling on them to encourage research and development for neglected diseases and to address US-initiated Free Trade

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[118] In May 2003, the EC introduced a Regulation to avoid trade diversion into the European Union of certain key medicines purchased under tiered pricing system. The Regulation focuses primarily on Malaria, Tuberculosis and HIV/AIDS. See European Communities 2003: http://trade-info.cec.eu.int/cgi-bin/antitradediversion/annual_reports.pl?action=reports

[119] See http://trade-info.cec.eu.int/civilsoc/meetlist.cfm?pastyear=2005

[120] Seco Gerard. MSF Access Campaign: EU Liaison Officer. Interview by author.

[121] The message conveyed is well represented by the following NGO Joint Statement available at http://www.cptech.org/ip/wto/p6/ngos12032005.html

Agreements that require signatories to implement and enforce more stringent IPR protection than is required by the TRIPS Agreement.[122]

In intergovernmental negotiations, a legal debate ensued over how or indeed whether to incorporate the August 30 Decision into the TRIPS Agreement. In two separate filings with the TRIPS Council, the European Union[123] and the United States[124] took the position that it was just a technical matter of incorporating the Decision into the TRIPS Agreement. The United States, in partnership with Japan and Switzerland, went further by insisting that the Chairperson's Statement should be made part of a permanent solution.[125] Indeed, the inclusion of the Chairperson's statement and demands to elevate its legal status by an explicit written reference to it in the text of the Amendment became a focal point for negotiations during 2005. The research-based pharmaceutical industry in particular, insisted that this be part of a permanent solution to the paragraph 6 problem.

However, the African Group, strongly supported by NGOs, was reluctant to make permanent a solution that was, in its view complicated, untested in practice, and reached under duress prior to the Cancun Ministerial Meeting.[126] Instead, the African Group took the view that negotiations on finding a permanent and satisfactory solution would continue during the amendment process. In a 2004 proposal for amending Article 31 of the TRIPS Agreement, it proposed dropping many of the safeguards and procedural requirements of the Decision including those concerning notification and trade diversion and adding a second sub-paragraph on when Article 31(f) did not apply.[127] The African Group also took the position that the Chairperson's statement would be an unnecessary addition to the amendment since it had fulfilled its purpose by creating conditions for consensus prior to the Cancun Ministerial Meeting.[128] Despite the strong stance taken by the African Group, many other developing countries were suffering from negotiation fatigue and were less hopeful that better terms could be achieved in the amendment process. Thus a split emerged between developing countries over how to proceed with the amendment process.

Despite hopes for a more efficient solution and against the backdrop of resistance from members of the Access Campaign, WTO members agreed to translate the August 30 Decision into the TRIPS Agreement by adding a formal amendment, "Article 31*bis*."[129] To the disappointment of Pharma, the US eventually backed down on the matter of the Chairperson's Statement under pressure from the European Union and developing countries. WTO members settled on the reading of the Chairperson's Statement in the General Council at the moment of adoption of the amendment. Nonetheless, it is possible that the Statement will serve as the sole supplementary means for interpreting the Amendment, should a dispute arise.[130] Although it remains unclear why the African

[122] Ellen 't Hoen 2005.
[123] Council for TRIPS 2003.
[124] Council for TRIPS 2005a.
[125] Council for TRIPS 2005a.
[126] Council for TRIPS 2004.
[127] Council for TRIPS 2004.
[128] The Decision reached on 30 August, 2003 did not include a reference to the Chairperson's Statement. However, it was later added as a footnote. The African Group argued that this was done without the consent or consensus of WTO members. See Rwanda's statement to the Council for TRIPS on behalf of the African Group, Council for TRIPS 2005b, para. 12.
[129] WTO 2005.
[130] ICTSD 2005; Abbott and Reichman 2007, 17.

Group would have agreed to a suboptimal solution, there was little hope of securing achievements in other areas at Hong Kong. It is speculated that developing country negotiators were eager to bring something substantive back to their national capitals. On the other hand, developed countries may have been trying to demonstrate their commitment to the "development" agenda at Hong Kong and thereby deflect attention away from the lack of progress on issues that tend to be of greatest interest to developing countries, namely Non-agricultural Market Access (NAMA) and Agriculture negotiations.[131] In any case, the outcome and thus the policy line adopted by EU negotiating officials at Hong Kong did not reflect the demands and priorities of public health advocates and NGOs. Since the interests of the European based pharmaceutical industry were contradictory, the EC's position represents a middle road between the strategic demands of patent holders and the generic industry.

Reactions to the Amendment varied widely. For instance, it was initially celebrated at the WTO as a great success. However, NGOs and public health advocates widely denounced the move. According to Ellen 't Hoen, Director of Policy Advocacy for the MSF Access Campaign, members of the WTO are "ignoring the day-to-day reality of drug production and procurement."[132] Furthermore, "it seems that the WTO has decided to sacrifice access to medicines before the Hong Kong meeting, settling for inadequate measures simply to get it off the agenda."[133]

The amendment does not take effect or become enforceable until at least two-thirds of WTO membership ratifies it. In the meantime, countries will continue to rely on the August 30 Decision. Since the substantive aspects of the decisions are identical, this distinction has little significance in practice. Nonetheless, in the absence of concrete evidence that the system will work to effectively meet global needs for affordable generic medicines, NGOs and public health advocates encourage WTO members not to ratify the amendment.[134] The original deadline for ratification was December 2007 but this has been extended to the end of 2009.

Before taking steps to ratify the amendment, the EU sought to create a legal basis in the EU for granting compulsory licenses for export. On 17 May 2006 the European Parliament and the Council adopted Regulation No 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.[135] This regulation effectively brought the EU Member States' patent regimes into line with the August 30 Decision. On 24 October 2007, the European Union officially ratified the TRIPS amendment.[136]

V. Conclusion

This paper traced the evolution of the EC's position on TRIPS and Access to Medicines across two key stages and studied the role of NGOs therein. In the run-up to the Doha Declaration in 2001, EU policymakers responded positively to demands by NGOs for improved transparency and public accountability and to opportunities for access and participation in the external trade policymaking process. These measures can be understood as part of a wider effort to legitimize the prevailing

[131] ICTSD 2005.
[132] ICTSD 2005.
[133] MSF 2005.
[134] For NGO reactions see http://www.cptech.org/ip/wto/p6/ngos12032005.html
[135] European Communities 2006.
[136] European Parliament 2007.

legal/liberal episteme and thus make it more sustainable by deflecting criticisms over the quality of decision-making. There is no doubt that NGOs, by virtue of their formal inclusion in policy discussions, worked to improve the procedural legitimacy of external trade policymaking in Europe.

Since NGOs working in the Access Campaign were willing to work within the WTO framework to find a solution to the access to medicines problem and also because they had such specialized, on-the-ground knowledge of the issue, they were invited to serve as key interlocutors in the policymaking process in the period preceding the Doha Declaration. By giving them a formal voice in policymaking, EU policymakers facilitated the role played by NGOs in disseminating information and generating public awareness about the links between stringent IPR enforcement and access to medicines. Through their role in both the Civil Society Dialogue and in informal meetings, NGOs were instrumental in educating policymakers about the ways in which the TRIPS rules were exacerbating the HIV/AIDS crisis in Africa. Through their media campaign and more formal public deliberations with EU policymakers, NGOs also generated and publicized debate over the issue. Through these channels, NGOs gave a voice to the world's poorest people who are unable to access affordable medicines and lobbied for more equitable allocation of burdens and benefits in the international trade regime. Finally, by holding policymakers accountable for their positions in international trade negotiations on TRIPS and Access to Medicines both within CSD meetings and in the media, decision-making during this period became more transparent and EU policymakers took greater public responsibility for their actions.

In terms of policy outcomes, the Doha Declaration was staunchly supported by EU policymakers and reflected, in many respects, the demands of NGOs working on the TRIPS: Access to Medicines issue. However, rather than mark a fundamental reorientation of the international IPR regime, the Doha Declaration was a political compromise designed to highlight already existing flexibilities in the system and to further ongoing WTO negotiations in other areas. Most analyses of the Access Campaign and many NGOs working on the issue did not fully comprehend the significance of the Paragraph 6 problem. As a consequence, activists and scholars alike prematurely celebrated the triumph of public health norms over stringent IPR protection and also the success of NGOs in influencing policy outcomes.

During the second stage of policy development, it became clear that the EC's position on TRIPS and Access to Medicines had not undergone a major substantive or normative change as a result of NGO involvement in the external trade policymaking process. Between November 2002 and December 2005, the task of solving the Paragraph 6 problem in the TRIPS: Access to Medicines issue became a highly technical, rather than political issue. EU experts and technocrats retreated from broadly participatory processes. Robust policy debates in formal consultative arrangements were replaced with top-down information sessions. Although NGOs continued to educate the public about the implications of the August 30 Decision and to disseminate information and lobby on behalf of people in developing countries, most activities occurred outside the context of formal consultative channels at the EU level. Where they had served as key interlocutors in the pre-Doha era, NGOs were now relegated to "informed observer" status in policy debates.

As the issue area became more technical, functional authority and decisive power pooled in the hands of technocrats and experts. They were required to develop new rules in a highly complex issue area that required the use of their specialized cause-effect knowledge to find a market-based solution to the

Paragraph 6 problem. EU technocrats and experts were the primary architects of the August 30 Decision. Their policy prescriptions served as the basis for new rules in the international trade regime, in the form of the TRIPS Amendment Concerning Article 31*bis*, and ultimately served to maintain and reproduce the ideas upon which the legal/liberal episteme is based.

The debate over appropriate solutions to the Paragraph 6 problem revealed deep ideational cleavages between EU technocrats and NGOs working on the TRIPS: Access to Medicines issue. EU technocrats are convinced that market based forces that uphold stringent IPR protection are sufficient to overcome the Paragraph 6 problem, provide equitably priced medicines to countries lacking sufficient manufacturing capacity and ensure research and development for infectious diseases in developing countries. They deliberately crafted a solution that is so fraught with bureaucratic red tape that it will scarcely be used in practice. Instead, EU technocrats expect that the mere threat of its use will compel patent holders to sell drugs at lower costs and shift their marketing strategies from a "low volume, high margin approach" to a "high volume, low margin approach." However, NGOs and Members of the European Parliament believe that relaxing IPR rules is essential to ensuring equitable access to affordable medicines.

It is not yet clear whether the TRIPS Amendment will have devastating effects for developing countries as NGOs fear. Since the mechanism has only been used once, it is unknown whether it will work to drive patent holder prices down or to promote competition between generic producers. What is clear is EU technocrats and experts, not NGOs or industry, were empowered in the EU's external trade policymaking process following the Doha Declaration in 2001. NGOs did not, by virtue of their formal participation in the process, compel EU policymakers to pursue a policy line on Paragraph 6 or the August 30 Decision that they would not have pursued in their absence. In other words, EU policymakers did not respond to NGO demands by pursuing policies that ensure greater access to medicines, reduce disparities in access to medicines between the north and south, and which prioritize public health concerns over IPR protection. Since this was an "Easy Test" for the Cosmopolitan explanation, we should be skeptical about the extent to which NGOs have the capacity to improve the substantive legitimacy of external trade policymaking in the EU.

This study has broader and significant implications for the legitimacy of the multilateral trade regime. Most would agree that if global or regional governance is to be sustainable, it must pursue just, equitable and fair ends. This taps into the broader view advanced by scholars such as John Ruggie that such social "embedding" – the idea that markets must be embedded in broader societal values or purposes, whether domestically or globally – is necessary for the ongoing legitimacy of an international liberal economic order.[137] This is precisely what NGOs tried to achieve in the TRIPS and Access to Medicines case.

Evidence of declining legitimacy entails, at a minimum, a decline in confidence amongst those affected by the rules in the ability of the governing arrangement to secure these values. It is widely acknowledged that WTO rules have thus far not distributed the benefits of membership in the international trade regime evenly. Persistent economic inequalities and widespread social injustices resulting from previous rounds of multilateral trade negotiations are entrenched and, indeed, exacerbated by new rules being negotiated during the Doha Round of Multilateral Trade Negotiations. International trade rules continue to privilege the interests of developed countries and

[137] Ruggie 1982; Polanyi 1944.

entrench rights for corporate actors. Evidence that the regime is unsustainable in the face of such inequities is increasingly present in ongoing multilateral trade negotiations. It is also evidenced by the recent profusion of bilateral trade agreements orchestrated by both the United States and the European Union. Thus, it is not controversial to say the international trade regime suffers from a crisis or, indeed, a loss of legitimacy. Given the findings in this paper, we must look to new means of altering power dynamics in the EU's external trade policymaking process and the international trade regime more generally if it is to be sustainable.

Improvements in procedural legitimacy alone are clearly insufficient. If embedded NGOs are to exercise their might and alter power dynamics in the international trade regime, their best hope is to build up their strategic policy capacity and technical know-how. Their talents should be further developed and used to help educate disempowered and marginalized members of the international trade regime both collectively and individually. Only by developing, articulating and defending autonomous policy choices can developing and least developed countries alter the patterns of empowerment in the international trade regime. NGOs could play a central role in helping these countries better control their fate by securing trade rules that pursue more equitable, fair and just ends. Considered in light of current negotiations on agriculture and non-agricultural market access (NAMA) in the Doha Round of Multilateral Trade negotiations, the need to alter the power dynamics in the international trade regime and build capacity in developing and least developed countries seem all the more pressing.