LOST IN TRANSLATION: THE CANADIAN ACCESS TO MEDICINES REGIME FROM TRANSNATIONAL ACTIVISM TO DOMESTIC IMPLEMENTATION

Tania Bubela* & Jean-Frederic Morin**

Canada was the first country to implement the WTO Decision of August 30, 2003, authorizing the export of generic drugs manufactured under a compulsory license to developing countries in response to a proposal brought forward by non-governmental organizations (NGOs) that now claim dissatisfaction with the Canadian legislation. This empirical case study examines what success means for an NGO campaign. It contrasts interviews, documents, media coverage, and public statements of stakeholders, using quantitative and qualitative analyses. It concludes the NGO network experienced a shift from a mobilizer of public sentiment at the international level to a policy adviser at the domestic level. This shift crystallized a change in leadership toward local, rather than transnational NGOs, and a shift in strategy from being radical to more reformist. While this process of institutionalizing the outcomes of international campaigns is necessary for the implementation of international norms into domestic policy, it required NGOs to compromise their ideal positions, producing some objective successes in legislative reform but subjective dissatisfaction of the NGOs in the failure of Canada's domestic regime to enhance access to medicines on the ground in developing countries.

---

* Tania Bubela**,** Assistant Professor, Department of Public Health Sciences, School of Public Health, University of Alberta and Member of the Law Society of Alberta.

** Jean-Frederic Morin, Assistant Professor, Université libre de Bruxelles.

The article was written while Dr. Morin was a post-doctoral fellow at the Faculty of Law, McGill University under the supervision of Prof. E. Richard Gold. The authors wish to thank Prof. Gold for his invaluable comments on the manuscript and encouragement throughout the research project, as well as Benjamin Taylor and Christopher Ali for coding and research assistance. The authors wish to acknowledge the financial support provided by a SSHRC INE (512-2003-1004; PI: E. Richard Gold) and a CIHR Ethics Operating Grant (EOG-79158; PI: E. Richard Gold).

Introduction

Lack of access to patented medicines in developing countries is again being raised in the Canadian Parliament.[1] This may come as a surprise to those who thought the issue settled in May 2004, when parliamentarians unanimously and with great fanfare adopted the *Jean Chrétien Pledge to Africa Act*,[2] later known as Canada's Access to Medicines Regimes (CAMR).[3] The *Pledge to Africa Act*, authorizing the production and export of patented medicines without the consent of the patent holders, received international praise from diverse sources, including the Irish rock star, humanitarian, and activist, Bono, UNICEF, the United States Trade Representative, and Pfizer. It also received significant Canadian media coverage despite its highly technical content in amending the *Patent Act*[4] and the *Food and Drugs Act.*[5] Canadians were left with the impression that their country had taken the lead in developing a meaningful and workable solution to access to medicines in developing countries. The Minister of International Cooperation at the time echoed a general opinion in her speech to Parliament: "We have a lot to brag about."[6]

---

1 Canadian HIV/AIDS Legal Network, News Release, "Move to Reform 'CAMR' Gains Momentum: New House of Commons Bill echoes Senate proposal, would ensure life-saving medicines reach people in developing countries" (25 May 2009), online: Canadian HIV/AIDS Legal Network <http://www.aidslaw.ca/publications/interfaces/downloadDocumentFile.php?ref=950>; Canadian HIV/AIDS Legal Network, News Release, "Dying for Lack of Medicines in Developing Countries: 43 organizations join in statement on the 5th Anniversary of Canada's Access to Medicines Regime (CAMR)" (14 May 2009), online: Canadian HIV/AIDS Legal Network <http:// www.aidslaw.ca/publications/interfaces/downloadDocumentFile.php?ref=946>.

2 *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa Act)*, S.C. 2004, c. 23 [*Pledge to Africa Act*].

3 Government of Canada, "Canada's Access to Medicines Regime," online : Canada's Access to Medicines Regime <http://www.camr-rcam.gc.ca>. CAMR is the result of co-operation between Industry Canada, Health Canada, the Canadian International Development Agency, the Canadian International Intellectual Property Office, International Trade Canada, and Foreign Affairs Canada.

4 R.S.C. 1985, c. P-4.

5 R.S.C. 1985, c. F-27.

6 *House of Commons Debates*, No. 043 (28 April 2004) at 1525 (Hon. Aileen Carroll).

CAMR was politically significant as the culmination of an intense campaign by international nongovernmental organizations (NGOs)[7] around the 2001 World Trade Organization (WTO)'s *Declaration on the TRIPS agreement and public health*.[8] This *Doha Declaration* called for international negotiations to address the need of countries without sufficient pharmaceutical manufacturing capacity to import generic medicines produced under compulsory licensing.[9] The *Doha Declaration* was necessary because the Agreement on Trade-Related Aspects of Intellectual Property Rights (*TRIPS*) provided that compulsory licenses "shall be authorized predominantly for the supply of the domestic market."[10] In effect, this provision in *TRIPS* meant that if a developing country did not possess sufficient manufacturing capacity, it was prevented from importing pharmaceuticals produced under compulsory licenses in another country. The *Doha Declaration* formally acknowledged that this situation was unacceptable, and required WTO members to negotiate an "expeditious solution."[11] After two years of difficult negotiations, WTO members adopted the *WTO Decision*, defining conditions under which a country could export pharmaceutical products to another under a compulsory license.[12]

On September 26, 2003, Canada became the first country to announce its intention to amend its *Patent Act*[13] to authorize the export of generic drugs manufactured under compulsory licenses.[14] The government was then faced with the difficult task of implementing the ambiguous terms of

---

7 Susan K. Sell & Aseem Prakash, "Using Ideas Strategically: The Contest Between Business and NGO Networks in Intellectual Property Rights" (2004) 48 International Studies Quarterly 143.

8 WTO, *Declaration on the TRIPS Agreement and Public Health*, WTO Doc. WT/MIN(01)/DEC/2, 4th Sess., online: WTO <http://docsonline.wto.org/DDFDocuments/t/WT/min01/DEC2.doc> [*Doha Declaration*].

9 *Ibid*.

10 WTO, *Agreement on Trade-Related Aspects of Intellectual Property Rights* at art. 31(f), online: WTO <http://docsonline.wto.org/DDFDocuments/t/UR/FA/27-trips.doc>.

11 *Supra* note 8 at para. 6.

12 *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540/Corr.1, online: WTO <http://docsonline.wto.org/DDFDocuments/t/WT/L/540C1.doc> [*WTO Decision*].

13 *Supra* note 4.

14 Heather Scoffield & Steven Chase, "Ottawa heeds call on AIDS" *The Globe and*

the *WTO Decision* (see Appendix 1[15]) while facing pressure from conflicting stakeholders. Stakeholders were also cognizant that the legislation would serve as a model for other jurisdictions.[16] Members of the government repeated in their speeches and press releases their goal of striking a "necessary balance" between the "competing objectives" of facilitating the flow of drugs to developing countries, complying with international obligations and maintaining the integrity of the domestic patent regime.[17] To this end, five

---

Mail (26 September 2003) A1. See also: James Orbinski, "Access to medicines and global health: Will Canada lead or flounder?" (2004) 170 CMAJ 224.

15 Appendix 1 compares and contrasts the key features of the *WTO Decision*, *supra* note 12, and the subsequent iterations of the Canadian legislation to implement it through Bill C-56, *An Act to amend the Patent Act and the Food and Drugs Act*, 2d Sess., 37th Parl., 2002-2003, and Bill C-9, *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chretien Pledge to Africa)*, 3d Sess., 37th Parl., 2004 (assented to 14 May 2004), S.C. 2004, c. 23. Appendix 1 also contrasts the contents of Bill C-393, *An Act to amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act*, 2d Sess., 40th Parl., 2009, which was recently introduced as a Private Member's Bill to the House of Commons by NDP Member of Parliament, Ms. Wasylycia-Leis. This last Bill addresses what are viewed in practice to be the major shortcomings of the CAMR and is supported by the Canadian HIV/AIDS Legal Network and other NGOs._Canadian HIV/AIDS Legal Network, "Dying," *supra* note 1.

16 The following jurisdictions also passed legislation to allow for the export of pharmaceuticals under compulsory license: Netherlands, India, Korea, the European Union, China, and Norway. Links to the legislative initiatives and brief descriptions may be found at CPTech, "Patent Exception for Exports to Address Health Needs," online: CPTech <http://www.cptech.org/ip/wto/p6/#Legislation>.

17 See for example, *Proceedings of the Standing Senate Committee on Foreign Affairs*, 37th Parl. 3d sess., No. 4 (12 May 2004) at 4:15 (Hon. Lucienne Robillard):

> Bill C-9 is based on a balance between different interests. They are, on the one hand, the great humanitarian goal of facilitating the exportation of essential drugs to developing countries. On the other hand, we must still protect the integrity of our intellectual property regime and make sure that our international obligations will be respected. It would have been impossible to develop this legislation without the goodwill, the expertise and the commitment of many stakeholders… We have managed to improve the legislation considerably while continuing to respect the necessary balance.

See also Industry Canada, News Release, "The Jean Chretien Pledge to Africa Act Approved by Parliament" (13 May 2004), online: Industry Canada

departments with different perspectives (Industry Canada, Health Canada, International Trade Canada, Canadian International Development Agency and the Department of Foreign Affairs) were fully engaged in the process of drafting the legislation. Moreover, the government integrated domestic and foreign non-state actors in the debate. Contrary to the usual procedure, the Minister of Industry requested that consultative workshops begin even before the first draft of the Bill and the memorandum to Cabinet were completed. Despite the difficult inter-ministerial dialogue and the extensive consultative process, the legislative process was rapid and Bill C-9 received royal assent on May 14, 2004.

Canada was not only the first country to amend its patent legislation to implement the *WTO Decision*, but was also the first to effectively use its compulsory licensing provisions. On September 20, 2007, the Federal Commissioner of Patents granted a compulsory license to Apotex to produce and export 260,000 packs of TriAvir, an HIV/AIDS combination therapy, to Rwanda.[18] To date, no other WTO member has issued a compulsory license

---

<http://www.ic.gc.ca/eic/site/ie1.nst/eng/02392.html>: "The amendments reflected the necessary balance between Canada's humanitarian objectives of facilitating the flow of life – saving pharmaceutical products to developing countries while maintaining the integrity of its intellectual property regime and ensuring that its international obligations in this area are respected;" Standing Committee on Industry, Science and Technology, *Evidence*, 37th Parl. 3d sess. No. 005 (9 March 2004) at 1130 (Patrick Smith), online: House of Commons Committees <http://www2.parl.gc.ca/CommitteeBusiness>: "How should the competing objectives of, one, ensuring that the drugs get to the people who need them in a timely fashion be achieved, and secondly, how can we do our best to ensure that the products are not diverted somewhere else?" And Standing Committee on Industry, Science and Technology, *Evidence*, 37th Parl. 3d sess., No. 002 (24 February 2004) at 1110 (Hon. Lucienne Robillard), online: House of Commons Committees <http://www2.parl.gc.ca/CommitteeBusiness>: "Ultimately, the government was confronted with the need to ensure that these amendments maintain the integrity of Canada's intellectual property regime for pharmaceuticals, while at the same time facilitating the flow of low-cost medicines to countries in need... the government has tried to create legislation that strikes an appropriate and effective balance between competing objectives, and I believe we have succeeded."

18 Apotex, Press Release, "Canadian Company Receives Final Tender Approval From Rwanda For Vital AIDS Drug" (7 May 2008), online: Apotex <http://www.apotex.com/global/about/press/20080507.asp>.

for export. Indeed, the WTO has received no further notifications from any exporting or importing country of its intention to do so under the system set up by the *WTO Decision*.[19]

Now Canada might become the first country to amend its implementing legislation. On March 31, 2009, the Liberal Senator, the Hon. Yoine Goldstein (since retired) introduced the private Bill (S-232) to amend CAMR.[20] Then, on May 25, 2009, a similar Bill (C-393) was introduced at the House of Commons by the New Democratic Party Member for Winnipeg North, the Hon. Judy Wasylycia-Leis.[21] Both bills are intended to facilitate the issuing of compulsory licenses by simplifying the conditions and requirements provided in the original CAMR (see Appendix 1).

S-232 and C-393 are actively supported by a group of Canadian NGOs led by the Canadian HIV/AIDS Legal Network and the Stephen Lewis Foundation.[22] These NGOs criticize the complexity of the process to obtain a compulsory license and consider it unlikely that another compulsory license will be granted soon. According to Richard Elliott, the Executive Director of the Legal Network, "the current system just doesn't work."[23] Stephen Lewis is even harsher, stating publicly, "We have failed lamentably."[24]

---

19 *Supra* note 12 at para. 6. The system set up by the *WTO Decision* is explained by the Information and Media Relations Division of the WTO Secretariat. See WTO, "Trips and Health: Frequently Asked Questions – Compulsory licensing of pharmaceuticals and TRIPS," online: WTO <http://www.wto.org/english/tratop_e/TRIPs_e/public_health_faq_e.htm>. See also Daya Shanker, "Access to Medicines, Paragraph 6 of the Doha Declaration on Public Health, and Developing Countries in International Treaty Negotiations" (2006) 2 Indian Journal of Law and Technology 8 at 10, n. 3. This paper makes the point that, "According to certain WHO officials, no country has yet issued a demand for compulsory licenses as authorized by the paragraph 6 solution of August 30, 2003. It has also been reported that the complexity of the Solution, along with the pressure on the needy countries not to take advantage of it, are the factors responsible for its non-use."

20 Bill S-232. *An Act to amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act*, 2d Sess., 40th Parl., 2009.

21 Bill C-393, *supra* note 15.

22 Canadian HIV/AIDS Legal Network, *supra* note 1.

23 *Ibid.*

24 Isabel Teotonio, "Clement vows to get cheap drugs flowing; Health minister

These criticisms by NGO actors require further analysis, since it is widely assumed that NGOs not only provided the impetus for CAMR, but were also the most influential actors during the drafting and legislative process. An article by Frederick Abbott is illustrative. According to it, "this legislation was introduced after Stephen Lewis, the UN Secretary General's Special Ambassador for HIV/AIDS to Africa, suggested that Canada implement the 2003 Decision [and] Prime Minister Jean Chrétien promptly took up the proposal."[25] But Richard Elliott, shortly after the adoption of CAMR, already expressed major reservations on the content of the legislation, stating it "falls short of fully reflecting the 'flexibilities' allowed under TRIPS and the WTO Decision."[26] Nevertheless Elliott considered that it "represents a victory of sorts for civil society advocates, whose intensive, sustained efforts had a major impact in improving the bill from its original form."[27] Nevertheless, "in light of its several defects, the bill in its entirety falls short of providing a 'model' that should simply be copied elsewhere. Rather, other countries should learn from the Canadian experience and avoid replicating these flaws in their own implementation of the WTO Decision."[28]

---

decries lack of aid. But current law prevents action" *Toronto Star* (14 August 2006) A1.

25 Frederick M. Abbott, "The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health" (2005) 99 Am. J. Int'l L. 317 at 332, n. 106.

26 Richard Elliott, "Steps forward, backward, and sideways: Canada's bill on exporting generic pharmaceuticals" (2004) 9:3 HIV/AIDS Policy & Law Review 15 at 19.

27 *Ibid.* at 16.

28 *Ibid.* The article goes on to list the main concerns with Bill C-9: that the government maintained a list of pharmaceutical products subject to compulsory licensing for export; concerns over the burdensome regulatory approval process for any pharmaceutical product manufactured under compulsory license for export; and an entity (e.g., an NGO) wishing to purchase and import pharmaceuticals produced by a Canadian generic producer under a compulsory license must first seek approval from the government of the importing country. On the positive side, Bill C-9 has a reasonable approach to royalties payable to the patent holder; Bill C-9 expands the list of countries eligible to use the mechanism beyond WTO countries, but still creates a "double standard between developing countries that belong to the WTO and those that do not" (at 19); Bill C-9 creates a price and profit cap for generic producers, but the actual process may

I. A Nuanced Understanding of Success for an NGO Campaign

This empirical case study attempts to explain the observation that while NGOs were considered the most influential actors during the policy process leading to CAMR, they claim a lack of success in and dissatisfaction with the outcome. This requires a nuanced understanding of success for an NGO campaign. The past two decades have produced a growing body of literature on the conditions for a successful campaign by NGOs.[29] These analyses generally correlate the number of NGOs or their activities with measures of success for lobbying efforts,[30] and minimize the situational realities for advocates seeking normative change.[31] Indeed, the success of NGOs in relation to the actual objectives of the NGO campaign has generally been assumed, not thoroughly assessed,[32] partly because there is little consensus on how to measure the success of an NGO campaign.[33] As Voss observes, "failure is an unpopular subject among social movement scholars."[34]

---

lead to unnecessary litigation by patent holders; and there is an unnecessary two-year limit on the duration of a compulsory license.

29 The variables considered in the literature include political entrepreneurs (Martha Finnemore & Kathryn Sikkink, "International Norm Dynamics and Political Change" (1998) 52 International Organization 887); discursive framing (Robert D. Benford & David A. Snow, "Framing Processes and Social Movements: An Overview and Assessment" (2000) 26 Annual Review of Sociology 611); political opportunities (William A. Gamson & David S. Meyer, "Framing Political Opportunity" in Doug McAdam, John D. McCarthy & Mayer N. Zald, eds., *Comparative Perspectives on Social Movements : Political Opportunities, Mobilizing Structures, and Cultural Framings* (Cambridge: Cambridge University Press, 1996) 275); and the attributes of particular issues (Margaret E. Keck & Kathryn Sikkink, *Activists Beyond Borders: Advocacy Networks in International Politics* (Ithaca, N.Y.: Cornell University Press, 1998).

30 David Chandler, *Constructing Global Civil Society: Morality and Power in International Relations* (New York: Palgrave MacMillan, 2004) at 44.

31 Rodger Payne, "Persuasion, Frames, and Norm Construction" (2001) 7 European Journal of International Relations 37 at 48.

32 Michele M. Betsill & Elizabeth Corell, "NGO Influence in International Environmental Negotiations: A Framework for Analysis" (2001) 1 :4 Global Environmental Politics 65.

33 Sidney G. Tarrow, *Struggle, Politics, and Reform: Collective Action, Social Movements and Cycles of Protest* (Ithaca, N.Y.: Cornell University Press, 1989) at 71.

34 Kim Voss, "The Collapse of a Social Movement: The Interplay of Mobilizing

This paper reflects more thoroughly on what "success" means for a NGO campaign. Success may be measured, as Heins suggests, at different levels: first in terms of real-world achievements of previously articulated goals, and second, in raising awareness and knowledge of the public and policy makers about a given issue.[35] To this is added gaining influence over a variety of stakeholders,[36] including the public, the media, the bureaucracy, and politicians through mobilizing information and political resources.[37] In addition to such objective measures, success also has a subjective component. While the official reports of NGOs are replete with success stories, many NGOs do not believe that they are successful,[38] an issue we also address in this case study.

This paper rejects three intuitive hypotheses. The first being that contrary to the general assumption, NGOs were not the most influential actors in the legislative process and, therefore, could logically be disappointed with the result – CAMR. Under this perspective, NGOs were wrongly perceived by other stakeholders as influential because, as a general rule, "NGOs can be expected to overstate their influence on negotiations and [policy makers] can be expected to understate NGO influence."[39] Alternatively, other stakeholders may have framed the *WTO Decision* and the Canadian legislation as an NGO policy success to avoid criticism. Since NGOs are seen as a source of legitimacy,[40] claiming their endorsement would be a rational strategy to improve the reputation of a much-criticized WTO, a pharmaceutical industry condemned for its greed, and a politically beleaguered Liberal government. Our empirical results, however, show that this hypothesis is unsustainable; NGOs were indeed the most influential actors in the legislative process leading to CAMR.

Second, one might hypothesize that NGOs refused to recognize their policy win for strategic purposes. They could seek to amplify the perception

---

Structures, Framing, and Political Opportunities in the Knights of Labor" in McAdam, McCarthy & Zald, eds., *supra* note 29 at 227.

35 Volker Heins, *Nongovernmental Organizations in International Society: Struggles over Recognition* (New York: Palgrave MacMillan, 2008) at 141.

36 *Ibid.* at 142.

37 William E. DeMars, *NGOs and Transnational Networks: Wild Cards in World Politics* (London: Pluto Press, 2005) at 62.

38 *Supra* note 35 at 140.

39 *Supra* note 32 at 76.

40 Alison Van Rooy, *The Global Legitimacy Game: Civil Society, Globalization, and Protest* (New York: Palgrave MacMillan, 2004).

of their own failure to maintain confrontational debates and generate a permanent impression of injustice. As Betsill and Corell observe, "there is frequently a gap between what NGOs publicly demand and what they privately hope to achieve."[41] However, this second explanation is equally unsatisfying. As this paper makes clear, there is currently a high degree of pessimism and cynicism among the international NGO community that a negotiated solution may be found to the issue of access to medicines for developing countries.[42] Indeed, international NGOs have moved from advocating for utilizing TRIPS flexibilities and patent law reform, to far more radical potential solutions.[43] NGOs that advocate for the reform of CAMR in Canada are, by comparison, among the most moderate and optimistic that a solution is still possible within the current framework.

Third, NGOs might have been initially satisfied with the outcome but learned from the first five years of CAMR that the mechanism is ineffective and requires amendment. It is generally recognized that actors do not have perfect and complete information and therefore cannot rationally calculate their preferred policy options at a given time.[44] Actors must accordingly draw learning from previous experience, meaning their preferences are continuously evolving. However, as this paper argues, some (but not all) NGOs that advocated for the implementation of the *WTO Decision* in Canada suspected from the beginning that the mechanism would not significantly improve access to medicines in developing countries, even if all their claims were incorporated in the legislation.

The more convincing hypothesis is the following: while the process of institutionalizing the outcomes of international campaigns is necessary

---

41 *Supra* note 32 at 75.

42 Jean-Frédéric Morin & E. Richard Gold, "Consensus-seeking, distrust and rhetorical entrapment: The WTO decision on access to medicines" (2010) 16 European Journal of International Relations 563.

43 As discussed below, these more radical options include a general exception for pharmaceuticals for export purposes, patent pools for essential medicines, prize funds to replace patents as a spur to innovation, and technology transfer to increase domestic manufacturing capacities. Some of these options were also discussed in World Health Organization, *Public health: innovation and intellectual property rights*: *Report of the Commission on Intellectual Property Rights, Innovation and Public Health* (Geneva: World Health Organization, 2006).

44 Herbert A. Simon, "Bounded Rationality and Organizational Learning" (1991) 2 Organization Science 125.

for the implementation of international norms into domestic policy,[45] it requires NGOs to compromise their ideal positions, producing some objective successes, but also subjective dissatisfaction on the part of the NGOs. In the present case, at the international level, the leadership of the NGO campaign was provided by transnational NGOs active in Geneva.[46] When the campaign moved to Ottawa, Canadian NGOs took the lead.[47] With this shift in key leadership came a change in strategy from outsider protest to insider lobbying aimed at legislative reform. These strategies included utilizing a policy-oriented discourse and conventional communication tactics targeting key audiences: the media, the public, and politicians. While these actions were effective in engaging policy makers and gaining influence, the proposed reforms and mechanisms were interpreted by policy makers as less radical than intended by the transnational NGOs, leading to only incremental policy changes. In the end, the change in strategy succeeded in instigating legislative change but failed to result in real-world success in increasing access to medicines in developing countries.

II. Methods for Assessing the Success of an NGO Campaign

We employed three methods to assess objectively the different levels of success, defined as (1) real-world achievements of previously articulated goals; (2) raising awareness and knowledge of the public and policy makers about a given issue; and (3) gaining influence over a variety of stakeholders. In addition, detailed interviews with key actors allowed us to assess their subsequent subjective satisfaction with the outcomes. By triangulating these methods, we contrasted oral and written discourses, archives and *ex post* narratives, and the results of quantitative and qualitative analyses.

First, content analysis enabled us to assess directly the information dissemination function and influence of NGOs compared to other stakeholders. We collected newspaper articles, the main theme of which (>50%

45 Andrew P. Cortell, & James W. Davis, Jr., «How do International Institutions Matter? The Domestic Impact of International Rules and Norms» (1996) 40 International Studies Quarterly 451.

46 *Supra* note 7.

47 While local Canadian NGOs participated in international events and had worked with similar organizations in developing countries, they were not significantly involved in the Geneva negotiations.

content) was CAMR, using the search terms "Bill C-9" or "Jean Chretien Pledge to Africa" and other synonyms in the Factiva database from 31 August 2003 to 25 November 2006. We also collected media press releases from all stakeholders, Canadian Parliamentary Hansard transcripts, and government documents obtained under the Canadian *Access to Information Act*.[48] We manually coded these documents using the same coding frame to identify the influence of non-state actors.[49] The coders identified claims typical to industry interest groups or NGOs (Table 1). The coders also tracked the number of words quoted in newspaper articles and editorials and tracked the number of times the name of an individual or organization was mentioned without being quoted.

Second, we used Lexico3 to identify cases when journalists are strongly influenced by a specific press release without using quotations.[50] To be considered as un-sourced quotes, these sequences must include at least four words with a verb or five words without a verb and without quotation marks. We considered proper names, dates and professional title as only one word. We found 101 sentence fragments used in an article or editorial on CAMR published in one of the main Canadian newspapers (*The Globe and Mail*, *Finan-*

---

48 *Access to Information Act*, R.S.C. 1985, c. A-1.

49 Two coders used a standardized coding frame, working together for two weeks and then reconvening periodically to discuss issues that had arisen during coding. If discrepancies arose, the coders reached a common interpretation and kept a log of decisions. This is a common methodology for qualitative content analysis : see, for example, Tania Bubela, Heather Boon & Timothy Caulfield, «Herbal Remedy Clinical Trials in the Media: A Comparison with the Coverage of Conventional Pharmaceuticals» (2008) 6 BMC Medicine 35; Timothy Caulfield & Tania Bubela, «Why a Criminal Ban? Analyzing the Arguments Against Somatic Cell Nuclear Transfer in the Canadian Parliamentary Debate» (2007) 7 :2 American Journal of Bioethics 51; Tania M. Bubela & Timothy A. Caulfield, «Do the print media hype genetic research? A comparison of newspaper stories and peer-reviewed research papers» (2004) 170 CMAJ 1399. For a discussion of content analysis and coding, see Michael Quinn Patton, *Qualitative Research & Evaluation Methods*, 3d ed. (Thousand Oaks, Cal.: Sage Publications, 2002) at 452-471.

50 Lexico3 is a software program with lexicometric functions, including a tool to identify a repeated sequence of words in different documents. It is similar, in this respect, to anti-plagiarism software used in some academic institutions : Cédric Lamalle *et al.*, "Lexico 3," online: Lexico 3 <http://www.cavi.univ-paris3.fr/ilpga/ilpga/tal/lexicoWWW/index-gb.htm>.

Table 1. Claims used to measure NGO/Industry influence in newspaperarticles and parliamentary debates

Industry Typical Claims	NGO Typical Claims
Pharma as part of solution. E.g., (a) Pharmaceutical companies are already working on the ground, have experience in international development, and work in partnership with NGOs and international organizations; (b) They are part of the solution and must be involved with other stakeholders.	NGOs as part of the solution. E.g., (a) Big pharma is rich, powerful, driven by profit, and untrustworthy. By contrast, NGOs work for public good and are trustworthy; (b) NGOs should be directly involved and the government should eliminate the requirement that NGOs get the "permission" of the importing country.
Patents are not the main problem. E.g., (a) Poverty, corruption, and inadequate health infrastructure are serious obstacles to access to medicines; (b) Relaxing patent law could not significantly improve the access to medicines problem.	Patent as a major problem. E.g., (a) Patents are responsible for unaffordable drugs; (b) Competition drives down the prices of medicines; (c) Relaxing patent law could significantly improve the access to medicines problem.
Diversion issues. E.g., (a) Government should introduce measures to avoid re-exportation and increase transparency by proactively tracking such as special packaging or special colouring of the products.	Complexity of the mechanism. E.g., (a) The government should remove unnecessary red tape measures that dissuade generic manufacturers and developing countries from using the mechanism, including the right of first refusal, the list of eligible drugs, the list of eligible non-WTO members, and extra litigation rights.
Humanitarian in nature. E.g., (a) The legislation should remain a humanitarian venture; (b) No industry should make profit over developing countries.	Commercial in nature. E.g., (a) Generics should be allowed to make enough profit to ensure sustainable access to low cost drugs.
Balance of rights. E.g., (a) Government should seek a balance between the urgent need to deliver assistance and the long term need to foster R&D through IPRs; (b) Government should maintain the integrity of the patent system as it is necessary to create incentive for R&D.	No balance. E.g., (a) Government should make access to medicines a priority over R&D because the right to health is a human right and/or moral obligation; (b) Government should not try to find a balance.

cial Post, *Toronto Star*, *Ottawa Citizen*, *Vancouver Sun*, *National Post*) after being used in a press releases or an op-ed published by government officials, generic drug manufacturers, brand-name pharmaceutical companies, and NGOs.

Third, we performed a computer-based lexicometric analysis of our corpus of 73 press releases, 29 open letters, and 87 newspaper articles to understand better the campaign strategy and communications tactics employed by NGOs compared to other stakeholders. The corpus had 7535 different lexemes (number of different words) and 161,338 occurrences (total number of words). We used the SATO software program[51] to measure discursive variations among the five groups of actors: governments, NGOs, generic drug manufacturers, patent-holders, and media. To make these discursive variations more meaningful, we combined 579 different words (7.68% of the total) into 54 categories, resulting in the categorization of 23,576 occurrences (14.61% of total). A Z value of greater than 2.0 or less than -2.0 was considered significant: that is, the word (or the category) was used significantly more (positive Z) or less (negative Z) frequently than expected in a random set of documents.

Finally, we assessed subjective satisfaction with the outcomes of the NGO campaign of different stakeholder groups through semi-structured interviews, conducted between June 21, 2006, and November 20, 2007, with 3 Canadian politicians; 7 Canadian bureaucrats; 8 foreign bureaucrats; 12 representatives of Canadian NGOs (including Canadian branches of transnational NGOs); 9 representatives of foreign NGOs; representatives of generic drug manufacturers; 8 representatives of pharmaceutical companies; 6 representatives from intergovernmental organizations; and 2 academics (Appendix 2). These interviews improved our understanding of campaign strategies and goals, motivations of actors, and timelines of events. We also specifically asked interviewees for their assessment of their and other actors' success in facilitating access to medicines in developing countries and influence on the legislative process. The structure of the interview – its confidential and face-to-face nature and the opportunity for follow-up questions to probe statements more deeply – made this method more likely than public statements or questionnaires to reveal subjective beliefs.[52] We reached satu-

---

51 The SATO algorithm is based on chi-square distance: Université du Québec à Montréal (UQAM), «Système d'analyse de texte par ordinateur (SATO) 4.3,» online: UAQM <http://www.ling.uqam.ca/sato/index-en.html>.

52 See Patton, *supra* note 49 at 339-427.

ration, whereby no new theme arose, after 54 interviews. We used NVivo to perform a qualitative discourse analysis and coded 127 themes.[53] These codes, combined with public statements in press releases and other documentation following the legislative process, allowed us to assess whether, overall, different stakeholder groups were satisfied or dissatisfied with the legislative outcomes.

Our study design, however, has some limitations. It is based on the public record, interviews with some, but not all, stakeholders, and lacks access to discussions and negotiating positions adopted during confidential hearings and meetings. It allows us only to make indirect inferences about the knowledge mobilization function of NGOs, as we did not directly measure knowledge acquisition of target audiences. Moreover, this is one case study; generalizing the results would require further comparative case studies on other campaigns for the national implementation of international norms. Nevertheless, this methodologically rich case study provides a template for objectively assessing different levels of success for a transnational NGO campaign as it is operationalized nationally as well as the subjective satisfaction of key stakeholders in the outcomes.

III. From Public Mobilizers to Policy Advisers: A View of Campaign Strategy and Goals

It is widely recognized in the literature that a transnational network of NGOs created the political momentum necessary for the adoption of the *Doha Declaration* and the *WTO Decision*.[54] From the end of the 1990s, this network capitalized on controversial cases of access to patented HIV/AIDS medications in Thailand, Brazil, and South Africa,[55] and later on the anthrax crisis of 2001,

---

53 QSR International, "NVIVO 7," online: QSR International <http://www.qsrinternational.com/default.aspx>.

54 Debora J. Halbert, *Resisting Intellectual Property Law* (New York: Routledge, 2005); Ruth Mayne, "The Global Campaign on Patents and Access to Medicines: An Oxfam Perspective" in Peter Drahos, ed., *Global Intellectual Property Rights: Knowledge, Access and Development* (New York: Palgrave MacMillan, 2002); *supra* note 7; Ellen 't Hoen, "TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way From Seattle to Doha" (2002) 3 Chicago J. Int'l L. 27; *supra* note 8.

55 The United States has imposed trade sanctions under the "Special 301" that authorizes the US Trade Representative (USTR) to undertake a review of

to communicate its message to media and WTO negotiators. This message was framed in a simple and highly successful formula, equating patents with high prices, and therefore with the narrative of premature death.[56] Demonstrations in the streets of Washington, Paris, and Bangkok cast pharmaceutical companies as greedy multinationals, then juxtaposed these firms against images of the sick and dying in developing countries.[57] As an NGO interviewee recognized, framed this way, the problem of access to medicines became "an issue that's really very simple for people to understand."

The transnational NGOs' frame was internalized, amplified, and further dramatized by media. *The Guardian*,[58] *Le Monde diplomatique*[59] and *The*

---

intellectual property laws and practices in other countries and impose sanctions if a country has failed to revise its patent laws in accordance with TRIPS and other bilateral trade agreements with the United States that address IP protection. This includes revoking the ability to use compulsory licensing and parallel imporation for pharmaceuticals. Middle-income countries such as India, Brazil and Thailand have been threatened with sanctions: Jillian Clare Choen-Kohler, Lisa Forman, & Nathaniel Lipkus, "Addressing legal and political barriers to global pharmaceutical access : Options for remedying the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the imposition of TRIPS-plus standards" (2008) 3 Health Economics, Policy and Law 229 at 240-241. The most egregious example of the use of "Special 301," however, has been against South Africa, after the South African government introduced its 1997 *South African Medicines and Medical Devices Regulatory Authority Act*, No. 132 of 1992, that allowed the Minister of Health «to revoke patents on medicines and to allow for broad-based compulsory licensing to manufacture generic versions of HIV/AIDS drugs:» *supra* note 7 at 161. In addition, in 1998, 39 pharmaceutical companies filed a lawsuit against the government of South Africa over its *Act*. The suit was dropped in April 2001 under extreme international and NGO pressure: CPTech, "Court Case Between 39 Pharmaceutical Firms and The South African Government," online: CPTech <http://www.cptech.org/ip/health/sa/pharma-v-sa.html>.

56 *Supra* note 7.

57 Mark Weisbrot, "A Prescription for Scandal" *Baltimore Sun* (21 March 2001) A17.

58 Chris McGreal, "Aids : South Africa's new apartheid" *The Guardian* (30 November 2000), online : The Guardian <http://www.guardian.co.uk/world/2000/nov/30/aids.chrismcgreal>.

59 Salih Booker & William Minter, "Global Apartheid" *The Nation* (9 July 2001),

Nation,[60] among others, compared the lawsuit by 39 pharmaceutical companies against the South African government's legislation to enhance access to HIV/AIDS medication to Apartheid.[61] Interviewees from the transnational NGO community considered they "were really winning public opinion" and that they "won the first round." According to a bureaucrat, "public opinion was important in getting the key players to come to the realization that it was something that they should take on and become an advocate for." As the issue gained in prominence, attention by governments became unavoidable. A bureaucrat admitted that, "it was from that point, when this issue kind of hit newspapers, that I had to start paying attention to it." Another bureaucrat, sceptical about advocate claims, explained that his country "took the view that whatever the merits of the issue, this was a politically very hot subject we could not avoid."

During the initial stage of the international campaign, the transnational NGO network was led by a small number of organizations, including Médecins Sans Frontières (MSF), the Consumer Project on Technology (CPTech), Health Action International (HAI), and Oxfam.[62] Only these organizations had sufficient expertise and resources to catch the attention of major international newspapers and to lobby negotiators in the corridors of international organizations. Although some Canadian NGOs closely followed the issue and cooperated with other organizations overseas, no Canadian NGO became a leader in the transnational campaign that resulted in the *Doha Declaration* and the *WTO Decision*.

Canadian NGOs played a more active role after Canadian Cabinet Ministers Allan Rock and Pierre Pettigrew announced in *The Globe and Mail* their intention to implement the *WTO Decision* in Canada, to the surprise of their own civil servants and most NGOs.[63] The speed with which the debate on the implementation of the *WTO Decision* proceeded in Canada privileged those few NGOs already familiar with the international access to medi-

---

online: HighBeam Research <http://www.highbeam.com/doc/1G1-75833857.html>.

60 Martine Bulard, "Defining the World's Public Property : Aparthied of pharmacology" *Le Monde diplomatique* (January 2000), online : Le Monde diplomatique < http://mondediplo.com/2000/01/12bulard>.

61 CPTech, *supra* note 55.

62 *Supra* note 7.

63 Heather Scoffield &Steven Chase, *supra* note 14; Eric Reguly, "Vigilance still needed on drug patent laws" *The Globe and Mail* (27 September 2003) B2.

cines campaign. These NGOs included Canadian branches of transnational organizations actively involved in the WTO process and Canadian NGOs campaigning for health and development. Considering the time constraint and their limited resources, these NGOs quickly decided to coordinate their efforts, pool their resources, and operate from the base of a pre-existing coalition called the Global Treatment Access Group (GTAG). The clear and overarching goal of the CAMR campaign was to improve access to medicines in developing countries.

Although GTAG involved several organizations, its CAMR campaign was led, to borrow the words of an interviewee, "by a more elite group." These leading organizations were the Canadian HIV/AIDS Legal Network, Canadian branches of MSF and Oxfam, the Interagency Coalition on AIDS and Development, and the Canadian Labour Congress. These organizations met more politicians than other NGOs, were invited to comment on legislative drafts under confidentiality agreements, and testified in parliamentary hearings. Interviewees felt only these leading organizations had the capacity and the resources to scrutinize the proposals and analyze the legal details: "There were very few NGOs who could substantively contribute to that level of technical debate." Canadian NGOs without specific expertise on the issue followed these leading organizations and did not develop an alternative campaign. Such *follower* NGOs,[64] lacking resources and expertise, relied heavily on the analysis and recommendations of the more involved organizations. As an interviewee from the periphery admitted, "I was really going with the flow in terms of the expertise that was there."

Richard Elliott, then director of legal research and policy at the Canadian HIV/AIDS Legal Network, emerged among his peers as the most influential individual, "the greatest resource" and "the core where everything came together." An interviewee explained that, "when you look at something like [CAMR], because it's technical, then of course the people with the legal background emerge as the leaders in the group." But Richard Elliott did much more than provide legal analyses for other NGOs. He participated in the dialogue with actors outside of the network, met with politicians and bureaucrats, galvanized the coalition, and, as one interviewee said, "[sold] the campaign to other civil society partners." His organization issued the highest number of individual press releases, and in all the joint press releases

64 Clifford Bob, *The Marketing of Rebellion: Insurgents, Media, and International Activism* (New York: Cambridge University Press, 2005) at 19.

issued by GTAG, the Canadian HIV/AIDS Legal Network appears as the most often quoted NGO (566 words compared with 114 for Oxfam). This disproportion in NGOs' press releases is reflected in newspapers articles; Richard Elliott was the most often quoted NGO representative in the Canadian newspaper articles on CAMR.

The transnational NGO network that initially framed the debate at the end of the 1990s played a lesser role. HAI was simply not involved in the Canadian debate, having no regional offices in Canada. CPTech posted several news items related to CAMR on its web site, and even considered facilitating the first compulsory license application, but never actively campaigned in Canada. Among the group of NGOs that framed the debate in the 1990s, MSF was the most active in Canada. However, in the end, MSF issued a press release entitled "How Canada failed the international community."[65] More recently, MSF is no longer publicly visible in the campaign by Canadian NGOs for CAMR reform.[66]

Led by Richard Elliott, GTAG and associated NGOs adapted their strategies and discourses for a legislative process. They did not use protest tactics, and the campaign never became a social movement.[67] While agenda-setting may need radical action to attract attention, the more prosaic stages of policy formation, especially the legislative process, required a different set of strategies. Several interviewees expressed the view that the policy process became too complex to use a social movement as leverage to effectively reach policy makers. "It was so technical," one said, "so difficult to explain to a broad audience." As the issue was becoming more complex, mobilizing wider society, educating concerned activists, and keeping them informed of the legislative process would have required additional efforts on the part of NGOs. As one explained, "when you get to the nitty-gritty of policy selection, it is very time intensive because there is a lot of back and forth, you have to talk to a lot of people and so on." Another described the process:

---

65 Medecins Sans Frontieres, Press Release, "Bill C-9: How Canada failed the international community" (29 April 2004).

66 For example, MSF was not one of the 43 NGOs that signed on to the following press release: Canadian HIV/AIDS Legal Network, "Dying," *supra* note 1.

67 Social movement is defined as a large informal grouping of individuals who mobilize people and resources within wider society to influence an authoritative elite: John D. McCarthy, Jackie Smith & Mayer Zald, «Accessing Public, Media, Electoral, and Governmental Agendas» in McAdam, McCarthy & Zald, eds., *supra* note 29, 291 at 291.

"it's slow, it's time-consuming, and it requires a huge amount of expertise." Therefore, GTAG did not activate a broader social movement, and allowed the campaign to be led by a narrow circle of experts. "We just didn't have the human resources or the financial resources to get the level of support that was really needed for this."

Instead of leading a social movement, [68] the Canadian NGOs invested most of their energy in what one interviewee called "direct lobbying," i.e., trying to influence political decisions by participating in formal political arenas and seeking direct contact with policy makers. For example, NGOs distributed factsheets to Members of Parliament before the vote on CAMR; met with Ministers; gave testimony in front of the House of Commons Standing Committee on Industry, Science and Technology; had frequent discussions with bureaucrats; and commented on earlier drafts of the bill. They also used the media to reach policy makers by targeting mainstream and national newspapers, rather than local or underground media.

Moreover, Canadian NGOs adopted a distinct vocabulary and discursive trope to influence policy makers, abandoning traditional strategies aimed at influencing broader publics. One could have expected NGOs to use inflammatory language, amplifying the victimization of developing countries and delimiting artificial boundaries between good and evil. However, our lexicographic analysis, summarized in Table 2, shows that Canadian NGOs did not refer to concepts related to morality (e.g., *moral*, *immoral*, r*esponsibility*) more than the brand-name pharmaceutical industry. They avoided, unlike generic drug manufacturers, using the adjective *life-saving* or synonyms to describe pharmaceutical products. They referred to the policy process as a deliberation or a negotiation, rather than using antagonistic terms (e.g., *fight, clash, battle, conflict, pressure, dispute*), as the media did. Even more surprising,

---

68 Some initiatives were launched to reach a broad audience, but most of these were modest, local, and dependant on well-organized NGOs. These included a petition postcard, a protest in front of the headquarters of a pharmaceutical company, a demonstration outside the convention of the then governing Liberal party, and an e-action process whereby citizens could send e-mails to Government Ministers. The scale of these activities could not be compared to large demonstrations organized from 1998 to 2001 across the world to condemn the lawsuit opposing 39 pharmaceutical corporations against the South African government and asking for the re-negotiation of the WTO agreement on intellectual property.

Table 2. Lexical clusters used more frequently than expected by different stakeholders (indicated by Z values greater than 2.0 and calculated using SATO software)

Stakeholder	Terms	Z value
Brand Name Pharma	Innovation (*investment, science, invention, new, research*, …)	14.3
	Diversion (*corruption, diversion, transparency*, …)	3.0
	Health infrastructure (*facilities, clinic, doctor, hospital, nurse*, …)	4.6
	Aid (*help, humanitarian*, and *assistance*, …)	5.8
Government	Epidemics (*Malaria, Tuberculosis*, …)	13.0
	People (*Child, Kids, Women*, …)	3.4
Generics	Legal dispute (*court, litigation, sued, contentious, tribunal*, …)	8.0
	Price (*cost, affordable, dollars, prices, expensive, cheap*, …)	4.4
	Canada (*Canada, Canadian, Canadians*, …)	9.0
NGOs	Law (*amendment, act, provision, rules, treaty, regulation*, …)	9.3
	Honor (*legacy, commitment, betrayal, pledge, promise*, …)	3.0
	Reputation (*leadership, first, precedent, model, proud*, …)	5.6
Newspapers	Government (*government, Health Canada, Martin, Cabinet*, …)	8.5
	AIDS (*HIV, AIDS, antiretroviral*, …)	8.3
	African countries (*Africa, Sub-Saharan, Ghana*, …)	7.0
	Politics (*political, politics, politicization, politicians*, …)	2.8

they referred less than did government to words such as *child, children, kids, and woman.*

In fact, Canadian NGOs used a legal, technical, and sober discourse to gain legitimacy with a policy maker audience, and pragmatically addressed the legalistic nature of affecting legislative reform. Their documents are characterized by an extensive use of legal concepts such as *amendment, legislation, act, provision, compliance, rules, treaty,* or *regulation.* They recognized the legitimacy of patent law and frequently referred to the *WTO Decision* as a model. For example, Canadian NGOs objected to the government's approach in applying compulsory licensing to only a set list of essential medicines and a provision granting the pharmaceutical patent holder the right of first refusal to contracts negotiated by generic drug manufacturers by claiming that neither reflected the "carefully-crafted international consensus."[69] They frequently used the WTO process to legitimize the *WTO Decision,* and argued that countries have "a particular responsibility to respect the international consensus achieved at the WTO after years of divisive debate, and should not unilaterally undermine that consensus."[70]

From the above discussion, we can conclude that the shift from international negotiation to national implementation was followed by a shift in leadership within the transnational NGO network. When the issue of access to patented medicines was still being negotiated at the WTO, the main actors in the NGO communities were large transnational NGOs. But once the *WTO Decision* was adopted and Canada announced its intention to implement it, Canadian organizations progressively took the leadership. Interestingly, a parallel phenomenon occurred with the industry network. The Geneva-based International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), that closely followed the WTO process, was one of the first to react to the Canadian initiative by warning the Canadian government that CAMR would be "a negative black eye" that could "very well affect the investment climate."[71]. But less than a week later, the Canadian Rx&D,

---

69 Canadian HIV/AIDS Legal Network, *Statement on Bill C-9, An Act to amend the Patent Act and the Food and Drugs Act* (Toronto: Canadian HIV/AIDS Legal Network, 2004), online: Canadian HIV/AIDS Legal Network <http://www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=449>.

70 *Ibid.* at 2.

71 Steven Chase & Drew Fagan, "Drug companies balk at Ottawa's AIDS plan" *The Globe and Mail* (27 September 2003) A1.

representing the very same companies, clearly took a leadership role and abandoned IFPMA's confrontational discourse.

IV. Success of NGOs in Influencing Key Audiences

We defined NGO influence as occurring when another stakeholder or other entity acted on information received from an NGO.[72] We assessed influence on the media, on political discourse, and on the evolution of the legislation.[73] Here we focus on the Canadian NGO community involved in the development of CAMR.

Influence on the media is an important indicator of public and policy maker exposure to issues and the contrary arguments made by the key stakeholders. Thus media analysis allows us to address influence directly, but is also indicative of the degree to which key stakeholders raise awareness and knowledge about a given issue. Interviewees identified mainstream national media as playing a key role in the process, and every category of actor invested substantial resources in media communication. For example, Rx&D, the main brand-name pharmaceutical industry lobby group in Canada, placed a full page advertisement in *The Globe and Mail* stating its position on CAMR. However, the fact that the national media was targeted, as opposed to local media and television, is also indicative of the intended audience of policy/decision makers and the social elite, rather than the broader public.

Our analysis reveals that the lexicon used by newspapers was closest to that used by NGOs (Z = 9.46 compared to 16.45 for generic drug manufacturers; 16.75 for government; and 20.00 for the brand-name pharmaceutical industry: SATO). An overview of the vocabulary shared by newspapers and NGOs shows, for example, that the word *flawed* appears frequently in both sets of documents. Moreover, the similarity between newspaper articles and NGO press releases increased over time, except in August 2006, when newspaper articles began referring more frequently than NGOs to concepts of morality and responsibility. This coincided with the International AIDS Conference in Toronto held in August 2006.

The similarity between the two sets of documents is partially explained by the fact that NGOs were the most often quoted actors (Figure 1). NGOs

---

72 David Knoke, *Political Networks: The Structural Perspective* (Cambridge: Cambridge University Press, 1990) at 3.

73 Keck & Sikkink, *supra* note 29 at 25.

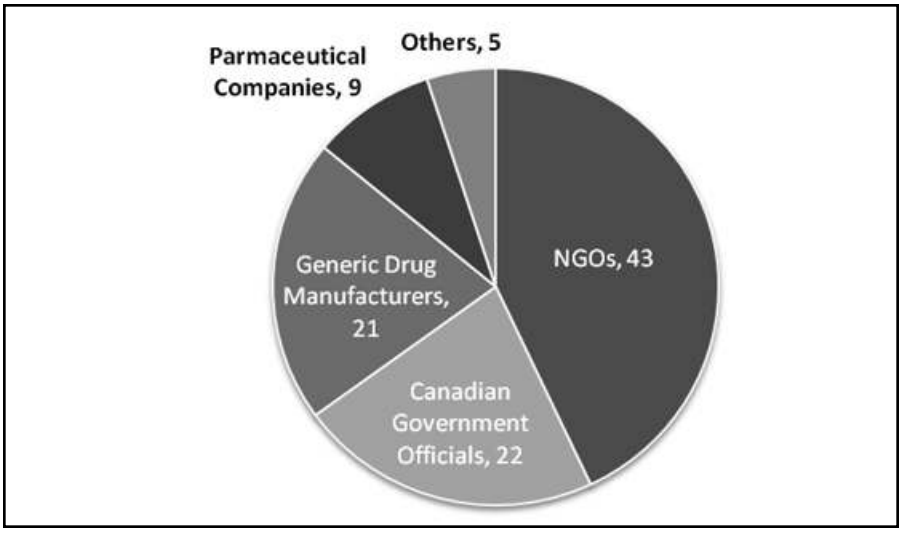

FIGURE 1. Percentage of words quoted from different sources in 87 newspaper articles and editorials on CAMR from August 2003 to November 2006. Most words quoted were from public figures supporting the claims of NGOs such as UN Envoy on HIV/AIDS, Stephen Lewis, and Bono, prominent social activist and lead singer of U2 (2483 words of 4058 for NGOs).

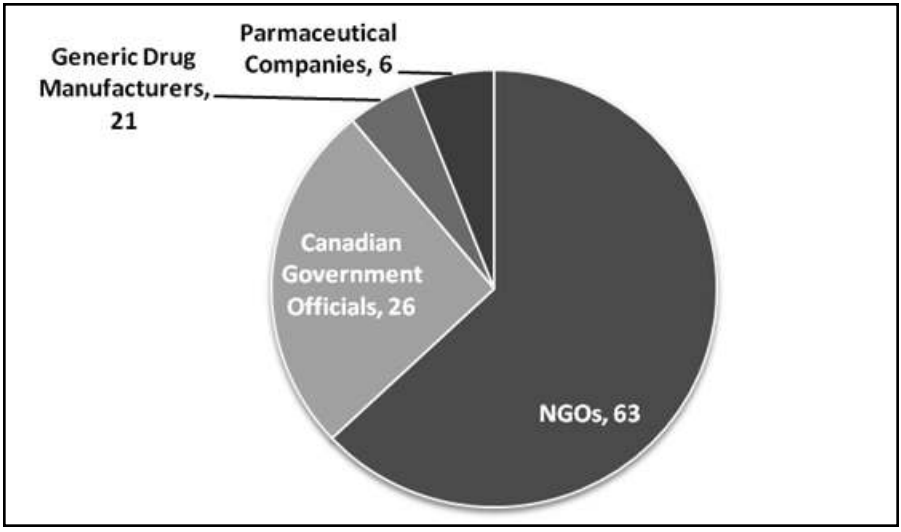

FIGURE 2. Percentage of the 101 repeated segments from different sources in 87 newspaper articles and editorials on CAMR from August 2003 to November 2006.

(24%) were also the most frequent entities named but not quoted in newspaper articles after politicians (76%). There were only four references to named entities from brand-name and generic industries. Journalists were also most likely to adopt NGO phrasing as their own (63% of "repeated segments" using Lexico3) (Figure 2).

Manual coding also confirmed that NGOs were most successful in communicating to media. As Table 3 indicates, the NGO claim that patents are a major obstacle to access to medicines (prognostic framing) and that the CAMR should remain as simple as possible (diagnostic framing) was

Table 3. Number of occurrences in newspaper articles and parliamentary speeches on CAMR of claims by the pharmaceutical industry versus claims by NGOs

	Industry Claims		**NGO Claims**	
Newspapers	Pharma as part of the solution	8	NGOs as part of the solution	1
	Patents are not the main obstacle to access to medicines	8	Patent are a major obstacle to access to medicines	55
	Diversion issues	13	Complexity of the mechanism	42
	Humanitarian in nature	42	Commercial in nature	20
	Balance of rights	14	No balance	4
Parliamentary Speeches	Pharma as part of the solution	8	NGOs as part of the solution	17
	Patents are not the main obstacle to access to medicines	11	Patent are a major obstacle to access to medicines	2
	Diversion issues	19	Complexity of the mechanism	33
	Humanitarian in nature	32	Commercial in nature	8
	Balance of rights	11	No balance	1

largely reflected in the media.[74] On the other hand, the claim for brand-name pharmaceutical industry involvement was mentioned more often than the idea of including NGOs, likely reflecting that NGO participation in the process (for example, as purchaser) was not challenged, while the provision giving brand-name pharmaceutical companies a right to take over a contract negotiated by a generic drug manufacturer with a developing country was highly controversial and, therefore, received greater newspaper coverage.

That said, not all NGO messages were transmitted by newspapers articles. One NGO claim (Table 3) that did not resonate with the media was that a mechanism based solely on humanitarian motivations could not sustain a predictable supply of drugs. Some NGOs considered it important that the generic drug manufacturers should make a profit when exporting drugs to developing countries, but this claim received coverage in only twenty newspaper articles. In addition, journalists tended to focus on AIDS and African countries, while NGOs tried to broaden the debate to include other health issues. This NGO strategy was in opposition to a fixed list of essential medicines under the CAMR. However, the concepts of HIV and AIDS were overrepresented in newspapers, and more general concepts related to health (for example, health, access, care, cure, treat, medical, healthcare) were underrepresented (Z = -12.57: SATO). The media rarely mentioned illnesses covered by NGO press releases, such as cancer, diabetes, pneumonia, and cardiovascular disease.

NGOs also argued against a specific list of least developed countries eligible under CAMR, stating the legislation should apply to all countries with insufficient manufacturing capacity in the pharmaceutical sector. But, contrary to NGO press releases, newspaper articles focused on African countries more than developing countries in other regions (Z = -5.99: SATO). The idea that the mechanism should provide a balance between different rights (access to drugs and patent protection) was also present in newspapers, which predominantly presented the industry view of this issue. This way of thinking (rather than a mechanism with the unique objective of increasing access to medicines) led to additional safeguards for the pharmaceutical industry and increased complexity in the regime.

---

74 The prominence of NGOs is less surprising when one considers that NGOs published more press releases and op-eds than other groups (62.6% of the total number of words in press releases and op-eds). This repetition of the message in multiple formats was likely a successful tactic for enhancing media coverage.

Nevertheless, overall, brand-name pharmaceutical companies were the least successful in their communication strategy with the media. Their press releases were characterized by references to innovation, the problems associated with the diversion of generic medicines, and discussion of lack of health infrastructure and pharmaceutical delivery systems in developing countries as the primary access issues, none of which resonated with the media. Only four editorials published in major newspapers supported the views of industry, while at least 14 supported NGO positions. Interviewees from industry felt that they were "not very good at dealing with the media" and that the sector as a whole was not highly ranked "in the court of public opinion." Industry felt that "they are on the defensive in the public's mind" and that those who support weakened patent protection "have more public exposure than the views of industry."

Our second level of assessment of influence is on parliamentary discourse. We coded all 106 of the main speeches made by parliamentarians in the House of Commons and during hearings before the Standing Committee on Industry, Science, and Technology between November 2003 and May 2004. As Table 3 indicates, some claims originating in NGO discourse were prevalent in the speeches, directly indicating NGO influence, and indirectly indicating success in the awareness raising function of NGOs. NGOs were seen as part of the solution, while it was taken for granted in enacting the legislation that patents were major obstacles to access to medicines. Parliamentarians, therefore, did not discuss this latter issue, as it was the starting premise, unlike newspaper articles that had to explain this issue. There was some discussion that generic industry should be allowed to make enough profit to ensure sustainable access to low cost drugs.[75] Parliamentarians focused on the humanitarian nature of the Bill but did not repeat the more subtle industry claim that the Bill should *only* be humanitarian in nature. The other industry claim supported by parliamentarians was the balance of rights: that government should seek balance between the urgent need to deliver assistance and the long term need to foster research and development through intellectual property rights.

Finally, NGO influence on the public debate and the legislative process was most clearly reflected in the evolution of CAMR. One interviewee from GTAG said, "there were basic conditions that we were looking for in the Bill [and] we got almost all of them." The NGOs could be credited with three

75 See "Commercial in nature," Table 3, above.

major reforms during the legislative process (see Appendix 1). The first was the removal of the so-called "right of first refusal." When originally introduced in Parliament as Bill C-56,[76] CAMR included a provision mandating that before a generic drug manufacturer could obtain a compulsory license, it would first have to offer any supply contract it had negotiated to the patent holder.[77] This provision was heavily criticized by NGOs and generic drug manufacturers, who called it the "right of first refusal."[78] It was the primary "flaw" mentioned in all NGO press releases and testimonies before the Committee.[79] In the opinion of NGOs, it would create a disincentive for Canadian generic drug manufacturers to negotiate with developing world governments because the deal may be taken over by the Canadian patent holder.[80] Ultimately, the government amended the Bill to remove this provision. Under the *Pledge to Africa Act*, a compulsory license will be issued if the generic company and patentee are unable to agree to the terms of a voluntary license after 30 days.[81]

The second major reform achieved by NGOs was related to the list of countries on behalf of which compulsory licenses could be issued. The first version of the Bill provided that countries that did not belong to the WTO, with the exception of least developed countries (LDCs), would be ineligible importing countries.[82] This provision was criticized by NGOs as creating a double standard between developing countries. Over 20 countries were neither WTO members nor recognized as LDCs. As Richard Elliott observed, "civil society advocates argued that access by people in the developing world to lower-cost generic medicines should not depend on whether their country belongs to the WTO."[83] As a result primarily of NGO advocacy, the government agreed to amend the Bill to provide that a country that is neither a

---

76 Bill C-56, *supra* note 15.

77 *Ibid.*, ss. 21.04(6)-(7).

78 Orbinski, *supra* note 14.

79 Lalita Acharya & Kristen Douglas, *Bill C-9: An Act To Amend The Patent Act and The Food and Drugs Act* (Ottawa: Library of Parliament, 2004), online: LEGISinfo <http://www2.parl.gc.ca/Content?LOP/LegislativeSummaries/37/3/c9-3.pdf>.

80 Orbinski, *supra* note 14.

81 *Supra* note 2, s. 21.04(3)(c).

82 Bill C-56, *supra* note 15, s. 21.03.

83 Richard Elliott, "Pledges and pitfalls: Canada's legislation on compulsory licensing of pharmaceuticals for export" (2007)1 International Journal of Intellectual Property Management 94 at 104.

WTO member nor an LDC is an eligible importing country if named on the OECD list of countries eligible for official development assistance and if faced with a national emergency or other circumstance of extreme urgency.[84] As one interviewee concluded, "you could clearly see the influence of the NGO movement in that."

The third reform was the expansion of the categories of eligible purchasers. The first version of the Bill defined the eligible purchaser as the government of the country or the agent of that government.[85] By contrast, the Bill as enacted refers to "the governmental person or entity, or the person or entity permitted by the government of the importing country."[86] An entity permitted by the government could be an NGO, such as MSF, which often plays a role in procuring and delivering medicines to patients. Mr. Éric Dagenais, from Industry Canada, explained in front of the Committee: "The amendment was based on testimony from the various NGOs who were concerned that the bill did not include any role for them."[87]

These major reforms were accompanied by several minor reforms, including the expansion of the list of pharmaceutical products eligible for export[88] NGOs repeatedly called on the government to make CAMR available for any pharmaceutical products, including active ingredients and diagnostic kits, for treating any health problem. While the government maintained a limited list of products that could be produced under the CAMR, it increased the list from 46 to 56 pharmaceuticals in response to NGO criticism.[89] Products on the list were derived principally from the WHO Model List of Essential Medicines[90] that, ironically, includes only medicines already accessible in developing countries. This odd policy of increasing access to already accessible medicines could be an effect of the discursive strategy of NGOs. NGOs might unintentionally have led policy makers to the WHO

---

84 *Supra* note 2, s. 21.03.

85 Bill C-56, *supra* note 15, s. 21.04(2)(f).

86 *Ibid.*, s. 21.04(2)(f).

87 Standing Committee on Industry, Science and Technology, *Evidence*, 37th Parl. 3d sess., No. 010 (20 April 2004) at 1230, online: House of Commons Committees <http://www2.parl.gc.ca/CommitteeBusiness>.

88 Bill C-56, *supra* note 15, Annex 1.

89 *Supra* note 2, Annex 1.

90 World Health Organization, "WHO Model Lists of Essential Medicines," online: WHO <http://www.who.int/medicines/publications/essentialmedicines/en/index.html>.

list by repeatedly employing the concept of "essential medicines" in their campaign, albeit in the context of the overall access regime.

NGOs were particularly pleased with the unanticipated pricing scale included in the Bill as enacted. The original Bill proposed a standard royalty rate of 2% of the value of the pharmaceutical products to be paid to the patent holder.[91] The final text provides for a sliding scale formula based on the ranking on the UN's Human Development Index with a 4% cap.[92] This amendment was later described by Richard Elliott as "one of the most positive features of the Canadian legislation" and "worthy of study by legislators and advocates in other jurisdictions as one possible model."[93] However, this amendment was not the result of NGO pressure, as most NGOs supported the initial approach.

NGOs had some losses in the legislative process.[94] First, the requirement of prior negotiation with the patentee was not waived in the event of national emergency. Second, at the request of the generic drug manufacturers, all products to be exported must meet the same safety, efficacy and quality standards as drugs destined for domestic consumption. Third, renewals of compulsory licenses are limited for the sole purpose of allowing a licensee to manufacture and export the quantity agreed to in the original license. However, none of these issues were publicly stated as high priorities in the initial NGO campaign.

According to Arts, to assess influence, one must establish that "A really intended to change B, A had access to B, the time lag between A's attempt and B's change is short, B's policy change is in A's interest, and B remained the same individual during the decision-making process."[95] Here, these criteria were met. On all assessments of influence, the NGOs were the most influential non-state actor, likely because of the conventional strategies they employed to influence institutionalized audiences such as government and the mainstream media. As interviewees from GTAG recognized, they "had a significant impact on the legislation" and "on the principle [they] have

---

91 Bill C-56, *supra* note 15, s. 21.08(1).

92 *Use of Patented Products for International Humanitarian Purposes Regulations*, S.O.R./2005-143, s. 8.

93 *Supra* note 83 at 107.

94 See Appendix 1.

95 Bas Arts, *The Political Influence Of Global NGOs: Case Studies On The Climate And Biodiversity Conventions* (Utretch, Netherlands: International Books, 1998) at 78.

won." CAMR balances the concerns of stakeholders but tips that balance towards the claims of the NGOs.

V. NGOs' Subjective Disappointment in the Outcomes

Several NGO representatives expressed mixed feelings when asked if they considered their efforts successful. They said, for example, that it is a "small but significant step," a "moral victory with unsatisfying effects," or "a victory that doesn't really count," of which they could only be "moderately pleased." In most cases, this ambiguity is the result of a conflicting assessment of their own influence and of the effectiveness of CAMR. On the one hand, they recognized that they "had a significant impact on the legislation." On the other hand, they consider that CAMR is unlikely to significantly improve access to medicines in developing countries.

When asking interviewees about their success, we did not specify what we meant by success. Some NGO representatives answered by referring to their short-term objective of influencing legislative reform; others referred to to their long-term objective of increasing access to medicines. When we analyzed the transcripts, we observed a marked difference in opinion between interviewees from peripheral Canadian NGOs and those from transnational NGOs with headquarters in Paris, London or Washington. Canadian NGOs, which were not initially part of the broader transnational network and were not doing significant field work in developing countries, tended to measure their success in terms of gaining legitimacy with local policy makers rather than in terms of the global effectiveness of their policies. When asked if they considered CAMR successful, few answer by referring to its effectiveness.

Overall, Canadian NGOs were the most enthusiastic. As one interviewee explained, "this was one case where we could put in our report, hey, policy changed." Indeed, their annual reports, memoranda to members, and press releases often presented CAMR as a major success. For example, a Press Release of the Canadian Labour Congress stated, "The labour movement successfully campaigned for the passing of the new Canadian law ... The public support of working families prevailed in this epic battle over the strong opposition from big pharmaceutical corporations."[96] When confronted with the fact that CAMR was not used before 2008, some representatives of Canadian NGOs argued that "even if it doesn't send any drugs overseas,

96 Canadian Labour Congress, Press Release, "AIDS: Canada Should Set Clear Goals for 2006" (28 November 2004).

[…] it does set a reasonably good benchmark for that legislation." Setting a precedent for a compulsory licensing scheme had, according to them, significant political value, irrespective of its effectiveness: it created a global momentum, raised awareness, and opened policy space. As a representative of a small Canadian NGO concluded, "the fact that we won on the political level is already a great step forward." Interestingly, this position was also expressed by small NGOs based in developing countries. For them, CAMR has a "political value" in their own country, as it could be presented as a demonstration that the use of TRIPS flexibilities by developing countries is supported and promoted by some developed countries.

Transnational NGOs that had initiated the international debate in the 1990s expressed less enthusiasm. One interviewee from a large transnational NGO, for example, dismissed the Canadian Bill as "a disgraceful mess" and another concluded that "we need to go back to the drawing board." They point to the fact that since CAMR's implementation in 2004, the process has only been used once. Moreover, these more sophisticated actors considered it unlikely that CAMR will ever provide enhanced access to medicines in developing countries. Further, they were afraid that the adoption of a legal mechanism will close the door for policy alternatives. Thus, reaching one objective, to gain legitimacy with an institutionalized audience was, paradoxically, disappointing for these NGOs that wanted more immediate impact in developing countries.

During our interviews, individuals working for transnational NGOs frequently expressed misgivings and regrets. Many were dissatisfied with the institutionalized strategies GTAG had employed. When we asked what they would have done differently, they considered that not using social movement tactics more intensively was a mistake. One interviewee reflected: "I think that were this to be done again it would be to not concentrate quite as much on what's going on at the government level and try and create more public awareness about the problems associated with the legislation." Another from a transnational NGO said: "We concentrated on direct lobbying and that's probably why we failed." Still others stated: "the most extraordinary lesson for me was the crucial importance of aggressive protest" and that certain colleagues did not have "the reflex to sort of make this campaign a campaign owned by the society as a whole."

Several reasons contributed to this difference in views between domestic and transnational NGOs. Small Canadian organizations explained that they considered themselves to be weak actors, without the capacity to initiate a global debate or create their own opportunities. One explained it had "limited human resources, certainly limited financial resources" and it is important

"to choose priorities for our advocacy and we choose them based on opportunities." Once the Canadian government announced its intention to implement the *WTO Decision*, the issue of access to medicines, described as "low hanging fruit," offered clear opportunities for late-coming domestic NGOs to join the negotiating process. Moreover, some of these were very familiar with the Canadian patent and political systems and, from their institutional perspective, were less inclined to have ambitious goals. As one interviewee recognized, "The more you get into that, the more you get involved in those discussions, the more you buy in a bit to the system, the more you start to realize things take time and people are doing their best."

In comparison, transnational NGOs were less reliant on short term policy wins, already had wide media exposure and legitimacy in the public eye, and received greater internal pressure for results on the ground. Reflecting on this, an interviewee explained that organizational connections to developing countries explained the difference in approach between the transnational and domestic campaigns:

> Many of the people we needed in the Access Campaign were not field people; they were experts in their field – intellectual property experts and pharmaceutical experts – and not field people. And it's different when you've worked in the field; you have a different link with the people. I mean, you've had people dying in your arms. It makes a difference to how you approach things, it makes a difference about the way you're passionate. Your instincts about it are different.

Transnational NGOs were the first to present the failure in achieving an effective mechanism as an opportunity to return to more radical strategies. Interviewees stated, for example, that "it should be a wakeup call," "there's going to be a big pullback," and "we just need to start from scratch." Canadian NGOs did not join them in this new framing. A representative from a Canadian NGO explained: "We fought so hard and we put so much time and energy into it, it's then hard to say afterward, well, my baby isn't quite as beautiful as I would like it to be." What Peterson calls an "asymmetry of understanding" started dividing issue entrepreneurs from latecomers.[97]

---

97 Karen Petersen, "Expanding Downs's Issue-Attention Cycle: International Terrorism and U.S. Public Opinion" (Paper presented at the 49th Annual General Meeting of the International Studies Association, San Francisco, 26 March 2008) at 10 [unpublished].

Conclusion

The *WTO Decision* was the result of a transnational NGO campaign.[98] However, once Canadian policy makers initiated legislative change in Canada, the NGO focus switched from the international arena, dominated by transnational NGOs, to the domestic arena, in which domestic NGOs took leadership. In making this switch, the campaign became trapped in a path that led to a narrow focus on the legislative process. At this final stage, institutionalized strategies appeared appropriate for meeting the goal of implementing the *WTO Decision* in Canada. In targeting an institutionalized audience, the domestic leaders of the NGOs had to compromise their ideal position, producing objective success in enacted legislation and influence over the media and policy makers. The NGOs were also successful in raising awareness of the issue and likely raising the knowledge of key audiences. This was the key benefit of the NGO influence on media content. However, NGOs were left with a hollow victory: a legislative scheme that is unlikely to address the primary goal of increased access to medicines in developing countries. Compromising their ideal positions, therefore, led to objective successes on some levels, but failure on the primary real-world goal of increasing access to medicines on the ground in developing countries. Consequently, this led to the subjective dissatisfaction of some, but not all, NGOs.

This division in subjective satisfaction of NGOs within the network occurred between smaller Canadian NGOs, focused on short-term institutional goals, and those NGOs that had been involved in the international access to medicines campaign. The latter, more established organizations were seeking the most radical change. They already had high levels of credibility and influence and were focused on results on the ground – increasing access to medicines in developing countries. Thus, transnational NGOs were more publicly and subjectively dissatisfied with the outcome when it became apparent that the CAMR process was unlikely to achieve its main goal.

Smaller NGOs, on the other hand, rationally employed strategies based on their strengths (conventional discourse, tactics and expertise) that successfully led to the enactment of CAMR, increased legitimacy and political influence and increased awareness of the issues of key audiences. As McAdam

---

98 Susan K. Sell, *The Global IP Upward Ratchet, Anti-Counterfeiting and Piracy Enforcement Efforts: The State of Play,* online: IQsensato <http://www.iqsensato.org/wp-content/uploads/Sell_IP_Enforcement_State_of_Play-OPs_1_June_2008.pdf>.

argues, reformist objectives (not revolutionist), formal entities (not social movement) and technical discourse (not dramatic) "decrease perceived threats and favour a positive response from an institutional audience."[99] Arts adds: "The more expertise NGOs bring to the negotiating table, the more influential they will be."[100]

It is not surprising that local and transnational NGOs play different roles during different stages of the policy process. It has been understood for some time that local actors sometimes lose control over their stories in transnational campaigns. In the political economy of humanitarian crises, the number of local causes seeking international support greatly surpasses the number of transnational NGOs. As Bob argues, "local movements insistently court overseas backing, and their promotional strategies count."[101] Because of this market dynamic, it is generally assumed that transnational NGOs have more control over a campaign than do local actors.[102] Transnational NGOs are even suspected of translating local testimony to fit with their own objectives. As a result, "there is frequently a huge gap between the story's original telling and the retellings- in its socio-cultural context, its instrumental meaning, and even in its language."[103] Our case-study, focusing on implementation rather than agenda-setting, suggests the reverse is also true. Here, transnational actors lost control over their story to smaller, local-based NGOs when the story was translated from an international to a national campaign.

So what lessons may be learned? Sell suggests that NGOs "must adopt a longitudinal perspective on IP negotiations or they will risk winning small battles (e.g., the Doha Declaration) but losing the war (e.g., access to affordable medicines)."[104] Both conventional and radical strategies need to be applied simultaneously, at all stages of the policy process, to gain multiple successes, in this case, domestic legislative reform and access to medicines.

---

99 Doug McAdam, "The Framing Function of Movement Tactics: Strategic Dramaturgy in the American Civil Rights Movement" in McAdam, McCarthy & Zald, eds., *supra* note 29 at 340.

100 *Supra* note 95.

101 *Supra* note 64 at 5.

102 Shareen Hertel, *Unexpected Power: Conflict and Change among Transnational Activists* (Ithaca, N.Y.: Cornell University Press, 2006).

103 Keck & Sikkink, *supra* note 29 at 19.

104 *Supra* note 98 at 5.

This means that the NGO community should not necessarily be reluctant to expose its internal divisions.

An interviewee working for an NGO recalled that when Canada announced its intention to implement the *WTO Decision*, "we knew very quickly, inherently really, because of the way NGOs work that we have to be together." But NGOs may need to consider working from two complementary networks with different objectives and tactics. NGO networks involved in the policy process have two competing objectives, one concerned with an increase in legitimacy of the challenging group, and the second with the distribution of new advantages to the group's beneficiary.[105] These two objectives are independent, as it is possible to achieve preemption (non acceptance with new material advantages) or co-optation (acceptance without new material advantages).[106] These partial outcomes are frequent since the set of strategies required for acceptance and material advantages are often conflicting. While serving as a credible source of information on a current issue requires predictability, moderation, and compromise, attracting attention to a new issue requires novelty, polemic, and confrontation.[107] NGOs may therefore need to consider working from two complementary networks with different objectives and tactics targeting different audiences to achieve multiple levels of success for different goals; divided, their distinct narratives may be stronger. As pointed out by Heins, "to succeed, campaigns have to both: mobilize targeted information and enlist the public and its passions."[108]

It appears, more recently, that some lessons have been learned from the CAMR experience. Transnational and local NGOs are currently pursuing different agendas on the access to medicines front. On the one hand, MSF and Knowledge Ecology International (the new name of CPTech) are moving toward a more radical agenda. Compulsory licensing for countries with insufficient manufacturing capacity is no longer their priority, as they advocate in Geneva for more ambitious objectives, such as a general exception for export purposes based on TRIPs Article 30, patent pools for essential medicines to reduce transaction cost for new combination and formula, prize funds to replace patents as a spur to innovation, and treaties on Research and

---

105 William A. Gamson, *The Strategy of Social Protest* (Homewood, Ill.: Dorsey Press, 1975).

106 *Ibid*.

107 Gamson & Meyer, *supra* note 29.

108 Volker Heins, *Nongovernmental Organizations in International Society: Struggles over Recognition* (New York: Palgrave MacMillan, 2008) at 142.

Development facilitating technology transfer to increase domestic manufacturing capacities in developing countries.[109]

On the other hand, the Canadian HIV/AIDS Legal Network, supported by 41 mostly small and local NGOs (along with Oxfam Canada and UNICEF Canada but not MSF), has maintained its reformist agenda and is moving forward with legislative reforms to streamline the CAMR process.[110] It is the driving force behind the two private member's Bills, one in the Senate and one in the House of Commons, that would amend CAMR to enable, among other reforms, generic drug manufacturers to send shipments of the same medication to multiple developing countries without needing new approvals for each shipment and to allow NGOs to purchase medications for distribution without first seeking the permission of the recipient country. However, these Bills have received little public attention and almost no media coverage,[111] indicating that momentum and political will in Canada may have been lost in the current Conservative-led minority Parliament.

Transnational and Canadian NGOs may work together again on the issue of access to medicines in developing countries when another international decisionrequires implementation within developed countries. While for now the two networks may follow parallel (and largely unconnected) agendas, it will, at that time, be critical to recall the important lessons learned from the implementation of the *WTO Decision* in Canada.

---

109 "The Global Politics of Pharmaceutical Monopoly Power by Ellen `t Hoen," online: Campaign for Access to Essential Medicines <http://www.msfaccess.org/main/access-patents/the-global-politics-of-pharmaceutical-monopoly-power-by-ellen-t-hoen/>.

110 Canadian HIV/AIDS Legal Network, "Dying," *supra* note 1.

111 A Canadian Newsstand search of media since the introduction of the first Senate Bill (from 1 March 2009) yielded only four results, three in support of the Bill, outlining problems with the cumbersome CAMR process : Gloria Galloway, « Bill on Medication Passes Second Reading » *The Globe and Mail* (3 December 2009) A4; Tanya Talaga, « All-Party Support Sought for Life-Saving Cheap Drug Initiatives » *Toronto Star* (5 October 2009) A12; Russell Williams, « Patent Reforms Help to Deal with African Crisis » *The Ottawa Citizen* (20 April 2009); and a letter in response to a further critical editorial by Michael Geist from Canada's brand-name pharmaceutical industry lobby, Rx & D. See « Medicines Regime Not Cumbersome » *Toronto Star* (18 April 2009) IN7.

Appendix 1:
Comparing CAMR with the WTO Decision, an Earlier Draft and a Current Bill

(**PA** = *Patent Act;* **FDA** = *Food and Drugs Act*)

	WTO Decision (August 30th 2003)	Canadian C-56 (Nov 6, 2003)	Canadian C-9 (May 14, 2004)	Canadian C-393 (May 25, 2009)
Eligible products	Pharmaceutical products are defined any patented products to address public health problem, including active ingredients and diagnostic kits (Decision, para 1).	List of 46 products, which may be expanded by the government (PA, Annex 1).	List of 56 products, which may be expanded by the government (PA, Annex 1).	Any drug, including monitoring products and products used in conjunction with a pharmaceutical product (PA, 21.02)
Eligible importing countries	Must have insufficient manufacturing capacity. LDCs are deemed to have insufficient manufacturing capacities. 23 countries opted out of the scheme and 11 countries stated that they will only use it in situations of national emergency. (Decision, para 1and annex)	Importing countries, except LDCs, must declare that they have insufficient manufacturing capacity. Countries of annex 4 must face national emergency. Except LDCs, countries that did not belong to the WTO are not eligible. (PA, 21.03)	Importing countries, except LDC, must declare that they have insufficient manufacturing capacity. Countries of annex 4 must face national emergency. Countries that are not a WTO member and not a LDC, has to be on the OECD list of countries eligible for development assistance and face a national emergency (PA, 21.03)	Any WTO members except the 23 members that voluntary opted out, any LDC, or any country on the OECD list of countries eligible for development assistance. (PA, 21.03)

Prior negotiations	Applicant should first seek, within a reasonable period of time, a voluntary licence from the patent holder. This requirement may be waived for extreme urgency, national emergency and public non commercial use (TRIPS, art. 31(b)	Before an applicant could obtain a compulsory licence, it has to offer its contract to the patent holder, which could grant a voluntary licence with 2% royalty or take over the contract on the same terms. No fast track in case of emergency (PA, 21.04(6)-(7))	If the generic producers and the patentee have been unable to agree on the terms of a voluntary licence for 30 days, the Commissioner shall issue a compulsory licence. No fast track in case of emergency (PA, 21.04(3)(c)).	No requirement of prior negotiation
Quantities	Only the amount necessary to meet the needs of the importing country (Decision, para 2(b)(i)	The quantity may not be more than the lesser of the quantity set out in the application or the notice of the importing country. (PA, 21.06(2))	The quantity may not be more than the lesser of the quantity set out in the application or the notice of the importing country. (PA, 21.05(2))	No restriction of quantities
Royalties	The right holder shall be paid adequate remuneration in the circumstances of each case, (TRIPS, art. 31(h) and Decision, para 3).	Standard royalty rate of 2% of the value of the pharmaceutical products exported (PA: 21.08(1))	Sliding scale formula based on the UN Human Development Index with a 4% cap (regulation)	A sliding scale formula based on the ranking on the UN Human Development Index with a 4% cap (regulation)

	WTO Decision (August 30th 2003)	Canadian C-56 (Nov 6, 2003)	Canadian C-9 (May 14, 2004)	Canadian C-393 (May 25, 2009)
Health and safety review	No requirement	The product shall be approved by Health Canada to ensure exports are of the same safety, efficacy and quality as drugs approved for sale in Canada (FDA, 37(2)	The product shall be approved by Health Canada to ensure exports are of the same safety, efficacy and quality as drugs approved for sale in Canada (FDA 37(2))	The product shall be approved by Health Canada under the same requirements as drugs approved for sale in Canada, or by the importing country, or by another jurisdiction with requirements at least as stringent as Canadian requirements, or by the WHO (FDA, 38)
Eligible	No requirement	The government of the country or the agent of that government (PA, 21.04(2)(f))	The government or an entity permitted by the importing country (PA, 21.04(2)(f))	No requirement
Duration of the licence	Duration shall be limited to the purpose for which it was authorized (TRIPS, art. 31(c)).	2 years cap with one easily obtain renewal but only for the quantity originally agreed when first issued (PA, 21.09 and 21.12)	2 years with one easily obtain renewal for the quantity originally agreed when first issued (PA, 21.09 and 2112)	No duration is provided. The authorization ceases to be valid when the holder relinquish the authorization (PA, 21.13)

Termination of licence	License shall terminate if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances (TRIPS, art. 31(g). The legal validity of any decision relating to the authorization shall be subject to judicial review (TRIPS, art. 31(i)).	Federal Court can terminate a licence where the patent holder establishes that the application contained incorrect information, the licencee has not complied with the requisite anti-diversionary measures or has failed to pay royalties, product has been re-exported in a manner contrary to the WTO Decision, or one of the prescribed terms of the licence has been violated (PA, 21.14)	Federal Court can terminate a licence where the patent holder establishes that the application contained incorrect information, or the licencee has not complied with the requisite anti-diversionary measures or has failed to pay royalties, or the product has been re-exported in a manner contrary to the WTO Decision (2114) Federal Court can terminate a licence on the grounds that the essence of the agreement is commercial in nature (generic producer is charging an average price that exceeds 25% of the patent-holder's average price in Canada. (PA, 21.17)	Federal Court can terminate a licence where the patent holder establishes that the licencee has not complied with the requisite anti-diversionary measures or has failed to pay royalties, or the product has been re-exported, with the consent of the holder or in a manner other than in the normal course of transit, to a country that is not an eligible importing country except when that country is party to a relevant regional trade agreement. The Federal Court may suspend its consideration for 30 days to allow the holder to remedy any deficiency identified in the application. (PA, 21.14)
Tech transfer	Members are encouraged to promote technology transfer and capacity building (Decision, para 7)	No provision on technological transfer	No provision on technological transfer	No provision on technological transfer

Appendix 2: List of Interviewees

Interviewee	Affiliation	Date of Interview
Abbott, Frederick M.	*Florida State University*	January 16, 2007
Addor, Felix	*Swiss Federal Institute of Intellectual Property*	February 14, 2007
Armstrong, Christopher	*Canadian International Development Agency*	January 17, 2007
Austin, Sara	*World Vision*	August 23, 2006
Bennett, Catherine	*Formerly with Pfizer*	October 6, 2006
Berger, Jonathan	*AIDS Law Project (South Africa)*	April 2, 2007
Blouin, Chantal	*North South Institute*	June 21, 2006
Bonin, Marie-Hélène	*Formerly with Médecins Sans Frontières*	November 8, 2006
Charles, Furaya	*Government of Rwanda*	November 20, 2007
Clark, Bruce and Hems, John	*Apotex*	January 30, 2007
Clark, Douglass	*Industry Canada*	November17, 2006
Connell, Jeff	*Canadian Generic Pharmaceutical Association*	January 30, 2007
Drummond, John	*Department of Foreign Affairs*	October 31, 2006
Elliott, Richard	*Canadian HIV/AIDS Legal Network*	January 31, 2007
Elouardighi, Khalil	*Act Up Paris*	October 30, 2006
Finston, Susan	*Formerly with PhRMA*	October 5, 2006

Interviewee	Affiliation	Date of Interview
Foster, John	*North South Institute*	September 8, 2006
Fried, Mark	*Oxfam*	September 8, 2006
George, Douglas and Boisvert, Julie	*International Trade Canada*	September 7, 2006
Gerhardsen, Tove Iren	*IP Watch*	November 1, 2006
Gorlin, Jacques	*Gorlin Group*	October 5, 2006
Jennings, Marlene	*Member of the Canadian Parliament*	October 10, 2006
Jorge, Fabiana and Cullen, Dolores	*MFJ International*	October 6, 2006
Kiddell-Monroe, Rachel	*Médecins Sans Frontières*	November 10, 2006
Kurji, Feyrouz	*Formerly at the Private Council Office*	January 10, 2007
Lee, David K.	*Health Canada*	September 8, 2006
Lewis-Lettington, Robert	*Genetic Resources Policy Initiative (Kenya)*	April 4, 2007
Lexchin, Joel	*York University*	January 31, 2007
Love, James	*Knowledge Ecology International (Formerly of CPTech)*	September 23, 2006
Matthews, Merrill	*Institute for Policy Innovation*	November 2, 2006
McCool, Terry	*Eli Lilly*	February 8, 2007
McCoy, Stanford	*United State Trade Representative Office*	October 6, 2006

Interviewee	Affiliation	Date of Interview
Musungu, Sisule	*South Center*	November 10, 2006
Noehrenberg, Eric	*International Federation of Pharmaceutical Manufacturers and Associations*	November 1, 2006
O'Connor, Michael	*Interagency Coalition on AIDS and Development*	November 8, 2006
Otten, Adrian and Watal, Jayashree	*World Trade Organization*	October 31, 2006
Passarelli, Carlos	*Government of Brazil*	December 13, 2007
Patry, Bernard	*Member of the Canadian Parliament*	November 8, 2006
Pettigrew, Pierre	*Former Canadian Minister of International Trade*	December 14, 2006
Pitts, Peter	*Center for Medicines in the Public Interest*	January 25, 2007
Pugatch, Meir	*The Stockholm Network*	December 20, 2006
Smith, Eric	*International Intellectual Property Alliance*	October 6, 2006
Smith, Patrick	*Intellectual Property Institute of Canada*	January 22, 2007
Spennemann, Christoph	*UNCTAD*	November 1, 2006
Sreenivasan, Gauri	*Canadian Council for International Cooperation*	September 7, 2006
Tamakloe, Joseph	*Ghanaian Patent Office*	November 16, 2007
Taubman, Antony	*WIPO*	January 17, 2007

Interviewee	Affiliation	Date of Interview
Twiss, Caroline	*Canadian Activist*	March 7, 2007
Vandoren, Paul and Ravillard, Patrick	*European Commission*	December 13, 2006
Van-Eeckhaute, Jean Charles	*European Commission*	December 19, 2006
Velasquez, German	*World Health Organization*	October 31, 2006
Weissman, Robert	*Essential Action*	October 5, 2006
Williams, Russell	*Canada's Research-Based Pharmaceutical Companies*	December 20, 2006
Yong-d'Hervé, Daphné	*International Chamber of Commerce*	December 5, 2006