

## Global health

## A tragically naive Canadian law for tragically neglected global health

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In May 2004 Canada's Parliament was the first in the world to subscribe to reforms enacted by the World Trade Organization, which promised to bring cheaper medicines to poor, epidemic-ridden developing countries. Parliament passed a new law, setting out an "access to medicines regime" that Canada's manufacturers of generic drugs could use to override the patents of brand name drugs in order to manufacture and export generic medicines according to the needs of governments and charities in poor countries. Canada's new law — the Jean Chrétien Pledge to Africa Act — was meant as a grand humanitarian project, and it got a fillip from numerous churches, labour unions, university groups, and especially nongovernment organizations such as the Canadian HIV/AIDS Legal Network and Médecins Sans Frontières, which lobbied vigorously for its passage.<sup>1</sup>

Parliament is now reviewing the law, 2 years after it came into force, but it faces this difficult reality: The law has never been used, and it has caused zero treatments to be manufactured for zero patients. Even the law's advocates concede that it "is failing to meet its goals."<sup>2</sup>

There are basically 2 competing theories for why the law has failed, and for what Parliament should do about it.

The first theory lays the blame at the law's complexity. Although it welcomed the law just 2 years ago, the Canadian HIV/AIDS Legal Network now believes that the law is "cumbersome ... to the point that it effectively deters those who might [use it]."<sup>2</sup>

In some ways, this criticism is correct. The law stipulates that charities and governments in poor countries, working with Canadian manufacturers of generic drugs, may apply to Canada's Commissioner of Patents for a "compulsory licence" — a type of patent override. But applications must be filed and processed singly; they cannot be shared by countries or charities who want to band together to submit joint applications to minimize the work of the application process.<sup>3</sup> Even successful applications are hobbled by the fact that a compulsory licence cannot last more than 4 years, after which the entire application process must begin again.<sup>4</sup> These national and temporal limitations make no sense alongside the global, chronic nature of epidemics such as HIV/AIDS, and they portend a churning bureaucracy of application-handlers if the law ever comes into common use. There is no reason why Canada has to have such an inefficient, user-unfriendly law.<sup>5</sup>

But before Parliament considers amending and simplifying the law, there is a second theory for why the law is not used: it is barely relevant, and it will remain so no matter how Parliament struggles to streamline it.

Contrary to popular belief, drug patents are extraordinarily rare in the developing world. In a study of 65 low- and middle-income countries, patenting was rare for 319 products termed "essential medicines" by the World Health Organization; only 17 of the essential medicines were patentable, although usually not actually patented, so that overall the patent incidence was low (1.4%).<sup>6</sup> Critics argue correctly that, within this 1.4%, there are certain instances in which patents cause exploitative pricing in poor countries; however, that reasoning focuses on rare exceptions and dresses them up as if to prove a rule.<sup>7</sup> The better-supported rule is that, where pharmaceuticals are covered by patents in poor countries, the manufacturers usually offer a donation or deep discount (as observed for 15 of 17 medicines studied<sup>6</sup>), so the patent's economic effect on price-setting is unlike raw monopoly power.

Thus, there are few patents, and most are voluntarily attenuated already. Accordingly, it stands to reason that opportunities to improve public health by overriding patent rights will be very rare.

Even in the isolated cases in which the overriding of patents might benefit public health in poor countries, Canada's manufacturers of generic drugs are unlikely sources of help. Lack of competitiveness is the reason. Simple economics argues that generic drugs made in Canada would tend to be pricier than those made in newly industrializing countries such as China and India, where the cost of wages, regulatory compliance and other noncapital inputs is traditionally less. Further, Canada's manufacturers of generic drugs are accustomed to charging such uncommonly high prices that selling to poor countries, at little profit, is out of character. According to the federal Patented Medicine Prices Review Board, prices of generic drugs in Canada exceed those in Australia, Finland, France, Germany, Italy, the Netherlands, New Zealand, Spain, Switzerland, the United Kingdom and the United States.<sup>8</sup> Even in tiny, remote New Zealand, generic drugs cost 77% less than those in Canada. All things considered, cash-strapped developing countries can get better value buying generic drugs from almost anywhere but Canada.

But possibly the strangest fact is this: the poor countries that might ask to import generic medicines made under com-

pulsory licence are, to date, simply not asking. Both the World Trade Organization and Canadian law require that, as a first step to issue a compulsory licence, the country wanting the generic medicines has to notify the World Trade Organization of the type and quantity of medicines it needs. That notification need not be complex: a brief letter will do, and Canada even helps with easy step-by-step instructions for lawyers to follow.<sup>9</sup> However, as of March 2007, the World Trade Organization reported that “no notifications have been made so far.”<sup>10</sup>

If poor countries are interested in compulsory licensing, curiously they have not taken advantage of it. The complexity of Canada’s law is not to blame, since the European Union, Norway, Switzerland, China and South Korea (31 countries in all) also have laws permitting compulsory licensing and exporting of medicines — and none of those laws have been used either.<sup>11</sup>

Taken together, these facts suggest that any amendment Parliament might contemplate to Canada’s law is bound to be fruitless. There is probably no amendment that, while remaining consistent with the World Trade Organization’s rules, could differentiate Canada’s law from those in the 31 other countries. Even if one imagined that Canada’s law could undergo a magic amendment to make compulsory licensing easy where 31 other countries have failed, the princely pricing of Canadian-made generic drugs would make that success nugatory.

None of this is to say that overriding patents is never justified. The appalling failure of manufacturers of brand name drugs to pool efforts and patents — for manufacturing co-packaged or co-formulated antiretroviral treatments that are convenient for first-line AIDS treatment in poor countries — was remedied only once manufacturers of generic drugs in India ignored patents and acted (although the fact that these same manufacturers in India patented their new co-formulations in Africa is a helpful reminder that even they are not impelled by altruism).<sup>12</sup> Some allowance in law must exist to prevent patents standing in the way of desperately needed inventions such as this.

But it is doubtful that Canada’s law can ever fill that role. One can plausibly argue that the law is not only a dead letter, but that groups such as the Canadian HIV/AIDS Legal Network and Médecins Sans Frontières did more harm than good in expending political capital to pass a law that resulted in zero treatments for zero patients. Patients would have been

far better served if those groups had instead spent the political capital to increase Canada’s foreign aid funding, or to reverse the brain-drain of African doctors. Setting a naive and ill-informed goal led to poor results. With the evident failure of Canada’s law, Parliament would be wise to cut its losses and concentrate on the more concrete things it can do to help the world’s poor.

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