

Compulsory licensing of generic drugs remains mired in quagmires

The goal was straightforward and highly-laudable: find ways of providing access to cheaper, generic versions of patented drugs in developing countries to combat public health crises resulting from HIV/AIDS, tuberculosis, malaria or other epidemics.

Yet, nearly a decade after global agencies began to pave the way for developing countries to buy or manufacture patented medicines at low prices to treat or prevent diseases, so-called compulsory licensing of generic drugs that are therapeutic equivalents of their patented counterparts (or what is often referred to as the “Doha declaration”) appears relentlessly mired in legal bogs.

Developed and developing countries squabble endlessly over aspects of the issue in world trade circles and courts. A World Trade Organization provision that aimed to allow developed countries like Canada to aid the cause by producing generics for export to countries with insufficient capacity to produce their own has yielded exactly one instance in which a drug was actually delivered to such a country.

In the developed world, governments and the brand-name pharmaceutical industry appear to find clever ways to undermine attempts to get cheaper generic drugs to needy nations, seemingly in the interest of protecting the health of their own pharmaceutical industry or, more specifically, the health of company bottom lines.

Meanwhile, India serves as the world’s supplier of generic drugs, essentially using a phase-in period in its compliance with international property rights law to mass produce cheap generic drugs for the developing world. China and Brazil threaten to step in to fill the void once India completes its transition to compliance.

In short, the world of patent protection for pharmaceuticals, and compulsory licensing exemptions therein, remains a



Reuters/Antony Njuguna

Getting cheap generic drugs to low-income nations to treat diseases such as AIDS has been more problematic than originally anticipated.

tangled, complex weave of policies, regulations and developments that, if nothing else, ensures that lawyers around the world are not lacking for business.

As to what impact compulsory licensing has had in nations facing public health emergencies, Ellen ‘t Hoen, senior advisor on intellectual property for UNCTAD, says that “while most countries’ national legislation contain provisions for use of compulsory licensing, it does not mean countries use it in practice.”

In Canada, the debate over compulsory licensing has primarily revolved around what is called “Canada’s Access to Medicines Regime” (CAMR), a framework built upon “An Act to amend the Patent Act and the Food and Drugs Act — The Jean Chrétien Pledge to Africa,” and subsequent regulations designed as part of the Canadian response to the World Trade Organization’s decision to allow member countries to produce low-cost generics for export in special circumstances.

It has been successfully used exactly once, and then only after considerable effort. In 2008, the generic manufacturer Apotex became the first and only

drug maker in the developed world to use the exemption when it shipped seven million tablets of Apo-TriAvir (a triple combination of zidovudine, lamivudine and nevirapine used to treat HIV/AIDS) to Rwanda. Yet, so aggravating and “cumbersome” was the process that Apotex said in a 2011 press release that it would be reluctant to go through it again unless changes were made (www.apotex.com/apotriavir/default.asp).

Critics of Canada’s regime, such as Richard Elliott, the executive director of the Canadian HIV/AIDS Legal Network, have charged that the legislation was essentially flawed on a wide variety of grounds: the list of pharmaceutical products that were eligible for export was too limited; the period of time that a generic could be exported was too short; the administrative roadblocks immense. A generic manufacturer had to file a licence application for every drug, for every amount produced and for every country to which it wanted to export a drug.

The framework “tends not to be particularly well-crafted for the realities of

the parties that need to use it,” Elliott says.

Efforts to eliminate some of the bottlenecks include a provision of a recent bill, “C-393: An Act to amend the Patent Act,” which enables manufacturers to use a single license to export a drug to a low- and middle-income country (www.parl.gc.ca/HouseChamberBusiness/ChamberVoteDetail.aspx?Language=E&Mode=1&Parl=40&Ses=2&Vote=142). Proponents argue that amendment would help, as generic drug companies could release several deliveries of a medication to a poor country over time.

The European Union has now enacted compulsory licensing legislation but none of its member nations have actually used the law to get generics to low-income nations.

Australia recently pledged to have legislation in place this year and Elliott surmises it could actually be the first “workable” law in the world.

The entire issue of compulsory licensing becomes that much more problematic once the impact of India’s 2005 adoption of new patent laws (to comply with the World Trade Organization’s Agreement on Trade Related Aspects of Intellectual Property Rights)

is factored in. Essentially, India has served as the pharmacy to the developing world but now must comply with international law in the manufacture of all drugs patented after 1995, though it can continue to manufacture generics that were in production prior to 1995.

Exactly how developments in India will shake out is unclear, Elliott says, adding that there is world-wide need for a straightforward application process where developing countries and generic manufacturers understand exactly how to apply for a compulsory license, as well as a need for specified formulas for calculating the level of royalties that will be paid to brand-name drug makers in cases where a knock-off is being produced.

Yet, for the most part, disputes over compulsory licensing legislation have been somewhat moot because India has been able to serve as a source of cheap generics for many nations, particularly those needing antiretroviral drugs to treat HIV/AIDS, t’Hoen says. There’s simply been no need for low- and middle-income countries to turn to the European Union or Canada, where they might get mired in diplomatic trade disputes, when the drugs were readily available from India.

That’s compounded by the fact the Europe has very limited production capacity to actually produce generics at a competitive price with facilities in India or China, where labour and active ingredient costs are much lower, she adds.

Even China can’t currently compete with India in the production of cheap generics but that may change in the future, because of industrial developments or differences in the schedules by which both countries move toward compliance with international law, says Jia Ping, a civil and commercial lawyer based in Beijing, China.

Eventually, though, as nations like India and China become fully compliant with international trade law, it will become critical that developed countries have laws and systems in place to be able to actually produce generics for low- and middle-income countries facing emergencies, Elliott says.

That’s why getting Canada’s legislation right is so important, Elliott adds. “Wherever we can get a workable model in place in the law, then that’s a model that could be replicated in other jurisdictions as well.” — Goldis Chami and Samuel Wasswa-Kintu, Vancouver, BC

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