

Concurrent Session C: Access to Essential Medicines

Moderator: Trudo Lemmens
Faculty of Law, University of Toronto

Trudo Lemmens, from the Faculty of Law, University of Toronto, welcomed the audience to the session on access to essential medicines.

Richard Elliott
Canadian HIV/AIDS Legal Network

Richard Elliott, from the Canadian HIV/AIDS Legal Network, focused on the international context of Canadian legislation, which was intended to supply generic medicines to developing countries. With respect to intellectual property law, specifically with patents, there is a fundamental tension between treating health as a commodity and as a human right.

Multiple sources are based on the premise that health and access to medicines are basic human rights, but those regimes are the “poor cousins” when it comes to enforcement. The World Trade Organization (WTO) and other groups that hold the powers of enforcement view health as a commodity.

“Law can be an enabler and a protector, but it can also be a barrier to public health,” Mr. Elliott said, referring to intellectual property law. “It can have a significant negative impact on access to medicines.”

The companies that hold patents for medicines become monopolies and charge monopoly prices that poorer countries cannot afford. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement indicated that patents do have a large impact on pricing as demonstrated by the cost differences between brand name drugs and generic drugs.

The WTO is an entity whose objective is to liberalize trade, yet intellectual property rights limit access to medicines, Mr. Elliott stated. There is a provision in the TRIPS agreement called compulsory licensing that enables generic drug companies to produce patented medicines without consent from the patent holder. Canada is the only country that has argued for an expanded version of this article, which has been only partially successful but holds a great deal of promise.

Giving legal obligation to a company other than the one that owns the patent is at the heart of the debate. This issue was brought to the WTO by developing countries because

of growing concerns about abuses by powerful countries and multinational pharmaceutical companies.

In November 2001, at a time when there were concerns about bioterrorism, developing countries defended their right to compulsory licensing while the United States and Canada argued that they needed to stockpile medicines in case of an anthrax outbreak. Developing countries forced the issue, and all member countries decided that the agreement on intellectual rights should promote public health and access.

One roadblock that exists for some countries is the absence of a pharmaceutical industry. They therefore need to have medicines imported from another country where an industry base does exist. In August 2003, the WTO agreed on a mechanism that would allow countries to produce generic drugs for import to another country that lacked the production capabilities.

Shortly after, Canada passed legislation called the *Jean Chrétien Pledge to Africa Act*, which would provide lower cost medicines to developing countries. The media has reported that since the act was passed, not a single pill has been exported, stated Mr. Elliott.

He then described how this process works: a developing country and a generic drug manufacturer would need to strike a tentative deal to produce a certain amount of drugs for a certain amount of time. The agreement then would be reviewed by Health Canada, which approves any drug sold to Canadians. The developing country then would have to go to the company that holds the patent and negotiate for a voluntary license. The proposal must be in the hands of the patent holder for 30 days. If a voluntary license is not granted, then the country could apply for a compulsory license, but certain conditions would have to be met first. A commissioner would fix a royalty rate, set on a sliding scale with a 4% cap on the royalty. The license would be limited to two years and would apply only to the specific quantity that was initially negotiated.

Until this legislation came along, an exported drug did not need to go through a review by Health Canada. Mr. Elliott said he questioned why there was such a concern and suspected they wanted to throw more hurdles into the process. He suggested a more streamlined process in which the generic manufacturer applies for and is granted a compulsory license on the condition that royalties are paid. Multi-country contracts then would be negotiated, which would bring prices down and would not expose countries to trade sanctions.

Jillian Clare Cohen
Faculty of Pharmacy, University of Toronto

Jillian Clare Cohen, from the Faculty of Pharmacy, University of Toronto, addressed the issue of corruption in the pharmaceutical industry and how it can be identified and fixed.

“When we talk about medicines, it’s not like shoes, computers or books. We’re talking about products that are life-saving and life-enhancing,” Ms. Cohen said. “What’s

disturbing is that there are so many good-intentioned initiatives, but yet we still have this very big drug gap.”

Corruption is a problem that aid agencies have only recently started to look at, Ms. Cohen said, adding that if there is corruption in the system, the poor are affected by it the most.

The pharmaceutical industry is susceptible to corruption, because it generates a lot of income. “It’s interesting, the kind of creativity that greed can inspire,” Ms. Cohen said.

Advances in technology make it harder to know which drugs are real and which are counterfeit. A significant amount of the drugs in developing countries are counterfeit or substandard, which forces people to go to drug peddlers or other illegal and dangerous means.

While there are many laws in place to curb corruption, there is a lack of enforcement, and penalties are very light. There are disconnects between the regulatory agencies, customs, and law enforcement as well as poor information dissemination, poor documentation, and very little critical review of fake drug statistics. Ms. Cohen added that it is not in pharmaceutical companies’ best interest to have fake drugs on the market.

She cited examples of possible corruption such as in Brazil, where a local manufacturer produced substandard contraceptive drugs and caused women to have unwanted pregnancies. And in 2004, GlaxoSmithKline concealed information regarding the side effects of the anti-depressant drug Paxil.

Through her work, Ms. Cohen developed what she called the Corruption Framework. It is a tool that can be used to identify vulnerabilities in a pharmaceutical business. The framework, built on Robert Klitgaard’s formula, consists of questionnaires for each decision point in the pharmaceutical sector.

“How do we fight corruption?” Ms. Cohen asked. “We need to know what the best practices are in each area and ensure transparency at all levels. If you find bad drugs, find out how and why it happened. Educate people, harmonize standards and best practices, and strengthen partnerships.”

Sarah Perkins

Access to Drugs Initiative, University of Toronto

Sarah Perkins, from the Access to Drugs Initiative, University of Toronto, told how the initiative began. In 2004, the Government of Ghana was looking for international sources of lower cost medicines, and Canada’s *Jean Chrétien Pledge to Africa Act* caught their attention.

One of the groups that got involved with the discussions between Ghana and Canada was the Faculty of Law at the University of Toronto. This group decided to undertake a review of Ghana’s legislation to determine if Ghana had the legal framework to access drugs from Canada. Ms. Perkins said they discovered that Ghana’s legislation was not

only compliant, it went above and beyond TRIPS, making it more difficult for Ghana to get a license.

Ms. Perkins and a law student from the university went to Ghana to meet with government officials about proposing changes to their legislation. Ms. Perkins' objective was to make sure Ghana could meet the minimum requirements, broaden its grounds to issue a license and establish an administrative regime.

“Projecting ahead for drug needs can be a tricky business,” Ms. Perkins said. “In the case of HIV/AIDS, not having enough drugs on the shelf can be a death sentence.” HIV/AIDS continually mutates, and the second generation of antiviral drugs is not available in Ghana. If a patient goes off the first line of treatment, they could face drug resistance.

Last year, Ghana issued the first compulsory license in its history and the first in all of West Africa, Ms. Perkins said. But it is still left with the question about how to help the rest of Africa. Ms. Perkins' suggestion is to unite the countries so that they increase their purchasing power and can negotiate with drug suppliers.

The General Agreement on Tariffs and Trade (GATT) exception could play a major role by waiving limitations for those countries belonging to a group. One country would issue the compulsory license as opposed to 10–12 countries issuing individual licenses. That one country would only export to others who share the same health problem. This solution, called regional procurement, would require political will and minimal national barriers, Ms. Perkins said.

She then outlined how it would work in practical terms: a regional secretariat would issue a tender and work with the country to obtain the compulsory license. For example, Ghana would issue a license on behalf of the other countries, then export the drugs to its neighbours, and payment would come from a central bank account. For the manufacturers, large purchases would create tax incentives, and the process would be simplified with only one purchaser and one administrative body to deal with.

“I want to stress that TRIPS presents us with some solutions, but we need to get the developing countries into the game to use those solutions,” Ms. Perkins said.

Questions and Discussion

“Within 10 years, the pharmaceutical industry might become a public good. Do you see any movement towards this, or is that completely out of the question?” asked one participant.

“An estimated 1300 children are dying every single day. We are trying to propose working within the existing framework, because it's faster to save lives today,” Ms. Perkins said.

Medicines are a public good although that is not reflected in the way the market is currently structured, Mr. Elliott said. He would be in favour of nationalizing the pharmaceutical industry. Canada is in a good position to bargain for more effective provisions, and Mr. Elliott suggested that a better system for research and development (R&D) could be established.

Ms. Cohen cited Brazil as an example of a public system that still has problems and suggested that different models need to be considered.

“Other than generic drug companies, are there other companies that are sincerely trying to make drugs more accessible?” asked another participant.

Generic companies are not innocent either and in some countries are actually more expensive. There are some companies with good initiatives, but Ms. Cohen said they are not good enough.

Mr. Elliott accepted that some multinational companies are running important programs and they do get points for that, but that is their only motivation for running them. It would be short-sighted for developing countries to rely on company philanthropy as the solution instead of putting proper market conditions in place.

In closing, a participant asked, “Who is ultimately accountable for tackling this huge issue? How do we hold them accountable? What can we do back at home to push that issue and advocate that something effective be done?”

Mr. Elliott suggested that Canadians push the government to be accountable and look at why the legislation on access to medicines has not worked so far. He also suggested getting universities to adopt intellectual property licenses so that they can share their R&D in this area.

When Ghana issued a compulsory license, it achieved a 60% saving, and many lives were saved, Ms. Perkins said. She suggested that even a little bit of education and support could empower developing countries to tackle this problem.