Annie Liang

Legal obstructions to access to essential medicines

Editorial

Canada has one of the highest life expectancies in the world, with an average life span at birth of 81.48 years relative to an average life expectancy of 51.86 years for a person living in Lesotho (World Fact Book, 2012). The huge life expectancy disparities within developed and developing nations can be seen as a significant indicator of quality of life, and be correlated with access to health care and the presence of disease. Many developing countries suffer from high degrees of political instability, while countries with the lowest life expectancies, such as Angola, Lesotho, and Zimbabwe, have increased rates of HIV/AIDS infections. The average per capita spending on pharmaceuticals in developed nations is one hundred times higher than in developing nations (Hunt, 2008, p. 10). The World Health Organization has estimated that in 1991 alone, roughly 15% of the world's population consumed over 90% of pharmaceutical output, and that increasing access could save up to 10 million lives annually (World Health Organization, 2004). The importance of this is reaffirmed in subclause E of the 8th Millennium Development Goal, which emphasizes the United Nation's commitment to "[cooperate] with pharmaceutical companies, [to] provide access to affordable essential drugs in developing countries" (Millenium Development Goals, 2000).

In order for medicine to be considered "accessible," it has to be available to all members of society, affordable, and of good quality. This is dependent on national health polities on medicine, reliable health systems, efficient distribution systems, and the availability of sustainable financing. In reality, access is severely limited by both national and international policies, rules, and institutions. Trade laws and intellectual property rights have generated immense debate over the value and role of pharmaceutical patents during health crises, including whether "the right to intellectual property for life-saving medications should take precedence over the right to health" (Westerhaus and Castro, 2007, S88).

Issues with Trade-Related Aspects of Intellectual Property Rights

Patents are the primary means of affecting the affordability of drugs and by extension, access to medicine. Established under the Paris Convention of 1883, a patent lasts for 20 years to prevent production, distribution and importation/exportation of industrial property where a patent exists (Westerhaus and Castro, 2007, S86). Each patent "must be filed in each country where the protection is sought within the span of one year from primary patent filing date" (Westerhaus and Castro, 2007, S86.) After the World Trade Organization's (WTO) Uruguay Round of trade negotiation between 1986-1994, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement was established in order to standardize intellectual property law among all World Trade Organization member states by 2005. This raised concern about access to affordable drugs and the future implications of public health for middle- and low-income countries, which make up two thirds of the 149 member states of the WTO (Westerhaus and Castro, 2007). TRIPS was later adjusted to allow the flexibility of compulsory

licensing in which generic copies of drugs could be manufactured without the consent of the patent owner solely within the country of demonstrated need for domestic use. However, the use to compulsory licensing is restricted to countries that have the infrastructure, resources, and domestic manufacturing capacity to create pharmaceuticals (New Gazette of Zurich, 2003) Developing countries that did not have the capacity to manufacture their own drugs could not import generic drugs either.

In 2001, the World Trade Organization met once again in Doha, Qatar to attempt to rectify the problems presented in TRIPS, releasing a statement that "affirmed the priority of public health over patent status" (Westerhaus and Castro, 2007, S85) and communicated that the "TRIPS Agreement does not and should not prevent members from taking measures to protect public health" (World Trade Organization, 2001). This later resulted in the creation of the Doha Declaration, which was met with mixed results. Developed countries, like the United States, sought to limit effect of the Doha Declaration within certain countries for specific epidemic diseases, as the US felt that the declaration could infringe on the rights of patent holders (Westerhaus and Castro, 2007, S86) A temporary waiver was eventually reached in August of 2003 that allowed countries without sufficient pharmaceutical manufacturing capacities to declare compulsory licenses and on the basis of a health emergency, import generic medicine (Westerhaus and Castro, 2006). Additionally, the least developed countries are not obligated to fully implement the provisions under the TRIPS Agreement until 2016, providing a transition period to allow the least developed countries to strengthen their public health sector.

The effectiveness of the advances made under the Doha Declaration and TRIPS is debated. Compulsory licenses, the primarily mechanism to increase access for desperately needed medicines, are in fact, rarely used and subject to strict conditions (Oliveira, Bermudez, Chaves, and Velásquez, 2004). Both importing and exporting countries must issue compulsory licenses, imported medicine is limited to the amount needed within the country, and must be clearly identified as being for humanitarian purposes only (Forman, 2007). While Malaysia, Indonesia, and Mozambique, and others have successfully issued compulsory licenses, countries are heavily discouraged from exporting drugs under compulsory licensing due to "persistent corporate and governmental threats of legal or economic sanctions and the complexity, cost, and limited duration and scope of the rules themselves" (Forman, 2007). The United States' placement of countries like India, Thailand and Brazil – some of the world's primary producers of high-quality generic medicine – on its 2010 annual trade "Watch List" indicates the acrimony surrounding the issue. These additions to the "Watch List," which advocates taking action against countries that the United States considers "inadequately protecting intellectual property,"(Medecins Sans Frontieres, 2010) serve to highlight the strong defensive position the U.S. has taken on the issue of access to medicine. Emi MacLean, U.S. director of Medecins Sans Frontieres' Access to Essential Medicines Campaign, characterized it as "using its trade laws to bully developing countries into applying arbitrary pharmaceutical industry requests at the expense of millions of people who depend on generic medicines in developing countries" (Medecins Sans Frontieres, 2010).

Generic Drugs and the "Big Pharma"

Generic drugs can be defined as pharmaceuticals whose active molecular compounds have been created as a copy of that of the original patent owner's or manufacturer's, giving it the same desired therapeutic effects at a much lower cost. Because of this diminished price, they are far more accessible than their brand-name counterparts, making their use ideal in developing countries. A 2004 survey conducted in Uganda showed that branded products were 13.6 times more expen-

sive than the recommended international price relative to 2.6 for generic drugs (Sentis, 2012). India alone, regarded as the "global pharmaceutical manufacturer of generic medication" (Tsui, 2011), produces roughly half the antiretroviral drugs developed for HIV/ AIDS within developing countries.

The topic of patents and generic drugs has generated debate between health activists and pharmaceutical companies. Pharmaceutical companies argue that patents are necessary to provide incentives for research and cover costs. Hence, the 20-year period for patents provides stability for pharmaceutical companies to recover research expenditures and prevent other pharmaceutical companies from profiting off their research. Generic medicine decreases the incentive for pharmaceutical companies to develop drugs, secure funding, and provide continued research. This was reaffirmed by Johnson and Johnson's unwillingness to license its patents for HIV drugs rilpivirine, darunavir, and etravirine into the Medicines Patent Pool; according to the pharmacetuical company's claim, "there is no urgency for making these drugs widely available in developing countries" (Medicins Sans Frontieres, 2012).

It is estimated that less than 5% of money spent for pharmaceutical research directly affect developing countries (Commission on Intellectual Property Rights). There is already little economic incentive and market to invest significant resources towards the needs of the poor within the developing world, and it is estimated that of the 1393 drugs developed between 1975-1999, only 13 were specifically for tropical diseases (Commission on Intellectual Property Rights). In contrast to research on HIV/ AIDS, there is relatively less work done on infectious diseases such as tuberculosis and malaria. No new tuberculosis drug has been developed for more than 30 years and some treatments require over 6 months to take effect (Commission on Intellectual Property Rights). Likewise, critics of pharmaceutical companies argue that a lot of research is publicly funded, and only a marginal proportion of profits obtained from selling patented drugs get funneled back into developing new drugs.

The argument for the use of generic drugs centres on the fact that increased competition results in a decreased price and more accessible medicine. The cost of antiretroviral (ARV) treatment by itself can exceed personal and national budgets. A report by the Intellectual Property Rights Commission states that between 2000-2002, the price of a branded triple therapy ARV treatment fell from $10,000 to $209 as a result of international pressure and generic drug availability (Commission on Intellectual Property Rights). It is only through open competition and the manufacturing of generic drugs that the drug prices can be pushed down, effectively decreasing barriers to access and making long term treatment financially sustainable.

New Hope in the Horizon?

Currently 39.4 million people are affected annually by HIV/ AIDS, compared to 300-515 million people who are affected by malaria and the 8 million affected by tuberculosis (Infoplease, 2007). The relationship between preventable disease mortality and socioeconomic status is obvious – it is estimated that 99% of people who die from these diseases live in the developing world (World Bank, 2011). However, there is much optimism for the future: the World Bank estimates that since 2010, 6.6 million people in low and m-iddle income countries have received ARV therapy. In addition, there was a 39% decrease in tuberculosis mortality for HIV negative people between 1990-2009 (Infoplease, 2007).

There have been various successes in the campaign for access to medicine as an essential human right. In 1988, researchers funded through the National Institute of Health at Yale University discovered the capacity of the compound Stavudine (d4T) as an

ARV drug in treating the HIV/ AIDS virus. This was subsequently patented and licensed to Bristol-Myers Squibb in 1994 (Westerhaus and Castro, 2007, S88). In 1998, pharmaceutical companies sued the government of South Africa over their Medicine Act in order to prevent compulsory licensing of patented drugs like d4T. Their case was later dropped in 2001 after protests by activist groups and immense international pressure. Likewise, Brazil has faced significant international pressure against its threats to issue compulsory licenses for efavirenz, lopinavir/ ritonavir and tenofavoir (Westerhaus and Castro, 2006). Since 1996, Brazil has instigated a national STD/ AIDS Program (NSAP) to make HIV/ AIDS treatment accessible to all its citizens free of charge through the national public health care system, which now treats about 1 in 6 of the nation's HIV/ AIDS patients and has decreased hospital admission by 80% since its implementation (Commission on Intellectual Property Rights). In 2001, the United States filed a complaint against Brazil for a perceived violation of Article 68 of the Brazilian Intellectual Property Law that "granted compulsory licensing if the patent holder does not produce a product locally within 3 years of granting the patent" (Westerhaus and Castro, 2007, S91). Brazil stated that it stands firm in its stance to prioritize the value of "public health over pharmaceutical matters" (Westerhaus and Castro, 2007, S91). The United States soon withdrew its claim under international pressure, allowing this to be seen as another victory for the access to essential medicine movement.

Today, there are various initiatives that greatly aid in making medicine more accessible. UNITAID created the Medicine Patent Pool in 2009, which collects various licenses for patented drugs, and allows faster and more efficient negotiations for generic ARVs. With a goal to "increase access to quality, safe, efficacious and more appropriate and affordable medicines, focusing on HIV/ AIDs" (Medicines Patent Pool, n.d.), the National Institutes of Health became the first patent holder to license the ARV drug darunavir into the patent pool (AVERT, 2012). The creation of the Global Alliance for Vaccines and Immunization (GAVI), in alliance with organizations such as WHO, UNICEF and the World Bank to increase access to vaccines and strength immunization systems, has prevented over 1.7 million deaths since 2000 (UN Department of Public Information, 2010).

It has been over 10 years since the Doha Declaration first reaffirmed the need to balance public health and intellectual property rights. ARV drugs prices have been heavily reduced due to generic competition and widespread distribution that has since resulted. Today, over 100 countries are in midst of implementing a national health care policy that can be used to advance pharmaceutical reforms (Virot, 2012). However, much is yet to be done. As stated by Medecins Sans Frontieres, throughout these past years we have seen "real achievements under our belt, [but] the battle is not yet won – there is still so much to fight for" (Medicins Sans Frontrieres, 2011).