

The drugs don't work: access to medicines in the developing world

Article (Submitted Version)

Guadamuz González, Andrés (2005) The drugs don't work: access to medicines in the developing world. Alfa Redi: Revista de Derecho Informático, 88.

This version is available from Sussex Research Online: <http://sro.sussex.ac.uk/id/eprint/46016/>

This document is made available in accordance with publisher policies and may differ from the published version or from the version of record. If you wish to cite this item you are advised to consult the publisher's version. Please see the URL above for details on accessing the published version.

Copyright and reuse:

Sussex Research Online is a digital repository of the research output of the University.

Copyright and all moral rights to the version of the paper presented here belong to the individual author(s) and/or other copyright owners. To the extent reasonable and practicable, the material made available in SRO has been checked for eligibility before being made available.

Copies of full text items generally can be reproduced, displayed or performed and given to third parties in any format or medium for personal research or study, educational, or not-for-profit purposes without prior permission or charge, provided that the authors, title and full bibliographic details are credited, a hyperlink and/or URL is given for the original metadata page and the content is not changed in any way.

	The drugs don't work: Access to medicines in the developing world
--	--

Andrés Guadamuz González*

Introduction

Development, poverty and the means to assist countries to break away from the causes of poverty have become some of the most important subjects in the international trade arena. Of these causes, the technological gap between developed and developing nations presents a compelling call for some sort of action in order to alleviate the resource inequality.

There are many examples that could illustrate that developing countries are being affected in some ways by the technological gap. Of these examples, one of the most important is the apparent struggle between large multinational pharmaceutical companies and developing nations with regards to access to medicines. This is because the question of health is one of the most important and contentious and evident indicators of poverty. This article does not pretend to be an exhaustive study of the issue of access to medicines, but some of the broader questions will be discussed in order to provide some evidence that strong international protection of technology may be affecting developing countries.

Health technology is the most critical technology sought by the developing world. When one takes a look at some of the worrying health figures in poor countries, one of the most striking facts is that many of the health problems faced by the inhabitants of these is that they are preventable, and can be addressed with some of the existing health technology enjoyed by the West. The problem then has to be one of resources and distribution, as multinational corporations own a large share of this technology. This article will deal mostly with the issue of access to medicines, but this is by no means the only concern when talking about the access of less developed countries to health technology.

1. The price of health

Amongst the many technological advances in health, pharmaceuticals are more likely to be owned than any other. Pharmaceuticals are essential for modern medicine, from antibiotics to vitamins, from vaccines to anti-retroviral treatments; one cannot imagine a healthy nation without proper access to the many treatments provided by pharmaceuticals. As Chetley points out, "*Modern drugs, used well, can help the less developed countries to speed improvements in health, but they cannot replace a lack of the necessary infrastructure to sustain better health.*"¹ This means that pharmaceuticals are not the only issue at stake when dealing with health, but it is one very important factor. In fact, every day 30,000 people die of preventable infectious diseases, bringing the total of those who die for those reasons to eleven million people per year.² Arguably, these are people who have a much greater chance of survival if they had access to the existing medicines that could potentially cure those diseases. Oxfam notes that:

* Lecturer in E-Commerce Law, University of Edinburgh.

¹ Chetley, A. *A Healthy Business? World Health and the Pharmaceutical Industry*, London: Zed Books, 1990, p.15.

² Oxfam. *Where is the money?* Oxfam petition to the G8 meeting in Genoa, July 20th, 2001. @:
<http://www.oxfam.org/what_does/advocacy/papers/G8Where'sthemoney.doc>

In sub-Saharan Africa today average life expectancy is 50 years--some 28 years less than the average for people in high-income countries. Treatable infectious diseases in the region account for 60% of deaths, while cancer and cardiovascular disease--the leading causes of illness-related death in the U.S.--account for only 15%.³

One of the reasons why these populations do not have access to the medicines that could save lives is because the price of health is high, as many medicines are owned by pharmaceutical corporations that either sell their products at high prices, or request that the developing countries purchase licences to produce or import those medicines. The result of this system is an obvious discrepancy between the prices of the medicines and the possibility of those who need them to acquire these required medicaments.

1.1 The pharmaceutical industry

The international manufacture of pharmaceuticals is largely in the hands of a number of multinational corporations that control large parts of the health market. As any other industry based in the capitalist system, the multinational pharmaceutical companies operate on a system that attempts to maximise profits and shareholder value. If that is the goal for these companies, they are certainly doing a much better job than any other industry in achieving those goals, as the profits and money involved in the pharmaceutical industry are staggering. In the year 2000, the pharmaceutical industry made \$20.3 billion USD in profits globally, with a percentage of profits against sales of 18.6%, higher than any other industry studied, including the automotive, entertainment and telecommunications industries.⁴ Globally, there are ten pharmaceutical companies in the Global Fortune 500 list, which have sales that total more than \$131 billion USD between them.⁵ This data does not even consider global giant Bayer, as they are diversifying in other fields and not only pharmaceuticals. In total, it is believed that the pharmaceutical industry will have worldwide revenue of \$406 billion USD in 2002.⁶ Of this total, North America accounts for 41.8% of the total pharmaceutical market, with 24% from Europe and 11.3% from Japan alone. In contrast, China and South East Asia account for only 5% of the total market, the Indian sub-continent 1.8% and Africa has only 1.3% of the market.⁷ This means that the pharmaceutical companies are staying away from some of the largest sections of the world's population.

The reason for this disparity is that pharmaceutical development is concentrated in some very few countries, mostly because to be successful in this industry there is a need to have considerable amounts of expenditure in research and development of new medicines. This is because the industry is highly competitive, and to remain competitive heavy spending is

³ Oxfam. *Oxfam International Report: Debt Relief Still Failing the Poor*. July 19, 2001. @: <<http://www.oxfamamerica.org/news/art655.html>>

⁴ Sanders, B. *New Figures Prove Pharmaceutical Industry Continues To Fleece Americans*. @: <<http://bernie.house.gov/prescriptions/profits.asp>>

⁵ Lekisha, D, Majchrzak, S. et al. *The Pharmaceutical Industry*. @: <<http://filebox.vt.edu/users/odin/project/overview.html>>

⁶ Hoen, E. and Moon, S. *Pills and Pocketbooks: Equity Pricing of Essential Medicines in Developing Countries*, Médecins Sans Frontières Report, 11 July, 2001. @: <<http://www.accessmed-msf.org/prod/publications.asp?scentid=318200146197&contenttype=PARA&>>

⁷ Harrington, M. *Brazil: What Went Right? The Global Challenge of Access to Treatment & the Issue of Compulsory Licensing*. Presentation made at the 10th National Meeting of People Living with HIV and AIDS, Rio de Janeiro, Brazil, 3 November 2000. @: <<http://www.aidsinfonyc.org/tag/activism/brazil.html>>

required to obtain new curative chemical compounds.⁸ Unfortunately, only few countries in the world have the resources to invest in the required levels of research needed to compete in this market. The United Nations Industrial Development Organisation (UNIDO), commissioned a report that classifies countries according to their pharmaceutical development capacity.⁹ Of these, only ten countries were considered to be able to produce a sophisticated output, and provide enough research to stay ahead. It is needless to say that these countries are considered developed. In contrast, only five developing countries were found to be capable of producing pharmaceuticals through imitation and reverse engineering – these countries are Argentina, China, India, Korea and Mexico.¹⁰ Most other developing countries were able to produce limited versions or dosages of existing pharmaceuticals, but were unable to produce any innovative chemicals. Most worryingly, 59 LDCs did not have a pharmaceutical industry whatsoever.

There are also some problems about the allocation of research in countries that have the capabilities to perform them. It is evident that under the present regime, there is a danger that research and development of drugs for illnesses affecting the developing world will continue to be under-funded, and that the money will be spent in high-return lifestyle drugs that are more profitable and sold almost exclusively in the developed countries, as is the case with drugs like Viagra, Zyban, Propecia, and Xenocal – evidence by the fact that 76% of all drugs approved in the US between 1989 and 2000 do not offer significant therapeutical benefits.¹¹ It has been pointed out that the problem with the way in which research is directed, is that it explicitly responds to profits, and not to the lack of research in that particular area. In fact:

Lack of scientific knowledge is not the major barrier to drug development - more is known about the biology, immunology, and genetics of leishmania and trypanosomes than any other parasites. Nor does the gap lie with technology, which has greatly benefited from recent advances. Policy issues seem to be the main obstacle to the translation of this knowledge into actual benefit for patients.¹²

The concentration of profits and research spending in some few developed nations have resulted in an industry that wields considerable economic power concentrated in one the mightiest economic industries on the planet. The industry's economic power has been translated to political power, as the industry has been generous in spending in lobbying and advertising. It is believed that in the year 2000 and in the United States alone, the members of the Pharmaceutical Research and Manufacturers Association (PhRMA) – the main pharmaceutical industry group – spent a total of \$360 million US dollars in lobbying and policy advertising campaigns. The main lobbying recipients were the United States Congress and other policy-making governmental organisations.¹³ But perhaps more worrying is the fact that the pharmaceutical industries has established very strong links

⁸ Cutler, D. and McClellan, M. "Is Technological Change In Medicine Worth It?" 20 *Health Affairs*, Sept/Oct 2001, p.21.

⁹ Ballance, R. et al. *The World's Pharmaceutical Industries: An International Perspective on Innovation, Competition & Policy*, New York: UNIDO, 1992.

¹⁰ Brazil should probably be part of this list.

¹¹ Love, J. *Evidence regarding research and development investments in innovative and non-innovative medicines.* @: <<http://www.cptech.org/ip/health/rnd/evidenceregardingrnd.pdf>>

¹² Zumla, A. *Drugs for neglected diseases*, July 1, 2002. @: <<http://www.msf.org/content/page.cfm?articleid=972C0953-CD52-4CB3-886584FC51391278>>

with the Bush administration. Industry members donated \$6.3 million USD to the Republican Party during the last elections, with the giant drugs company Glaxo-Wellcome donating \$1.2 million USD, while drug companies contributed \$1.7 million USD to the inaugural party of the then newly elected President G. W. Bush.¹⁴ As a result of this, even the most superficial analysis of the issue of drugs and less developed countries cannot help but notice how the interests of the United States and those of the pharmaceutical companies seem indistinguishable.

1.2 Pharmaceuticals and patents

From all of the intellectual property industries of the world, the pharmaceutical industry is the one that benefits the most from the existence of the patent system, as they are awarded with a limited monopoly in the products discovered during research in pharmaceuticals that allows them exclusive control of the exploitation, manufacture, and licensing of the work. One of the justifications for the existence of patents is to allow the inventor of a product to recuperate the economic investment incurred in the creation of that product, and to profit from its exclusive use. Because of this monopoly, the pharmaceutical companies can charge whatever seems fit to recover said investment. Part of the profits then goes towards future research and development of new drugs.

The reason for this particular benefit is that it is undeniable that the pharmaceutical industry is the field of innovation in which the justifications for intellectual property are more evident than in any other. Several studies have demonstrated time and time again that without patents the amount of innovations in pharmaceuticals would be greatly reduced. For example, a study of British pharmaceutical industries concluded that patents were vital for pharmaceutical industries because expenditure in research and development of new drugs would be reduced by 64% if there were no patents.¹⁵ In another classical study, Mansfield concluded that 68% of new pharmaceutical innovations between 1981 and 1983 would not have been developed without a patent system, far ahead than other industries.¹⁶

Despite the undeniable importance of patents, the amount of money spent on research and development does not seem to match the profits earned by the pharmaceutical industry. Representatives from the industry calculate that the amount of money invested in research and development totals \$30 billion USD globally per year, being only 7.3% of the total estimated income for 2002.¹⁷ What is more, the amount of money spent on research by the private sector does not really seem that impressive when compared to the amount spent by the public sector. As an example, in 1997 the pharmaceutical companies in the United States spent a total of \$18.9 billion USD in research, while the leading public sector research institution, the National Institute of Health (NIH), spent \$12.7 billion USD on that same year.¹⁸

¹³ Wexler, C. *Prescription for power*. Report for the Common Cause Education Fund, 2001. @:
<<http://www.commoncause.org/publications/june01/phrma/061201.pdf>>

¹⁴ Straub, B. "Drug industry welcomes Bush administration", *Nando Times*, January 21, 2001. @:
<<http://archive.nandotimes.com/business/story/0,1032,500302038-500483068-503321934-0,00.html>>

¹⁵ Silberston, A. *The Economic Importance of Patents*, London: The Common Law Institute of Intellectual Property, 1987.

¹⁶ Mansfield, E. "Patents and Innovation: An Empirical Study" 32 *Management Science*, 1986, p.175.

¹⁷ PhRMA. *The value of medicines*, 2001. @:
<<http://www.phrma.org/publications/publications/value2001/value2001.pdf>>

¹⁸ Pfizer. *The Value & Cost of Pharmaceuticals: Questions & Answers*, 2001. @:
<<http://www.pfizer.com/pfizerinc/policy/medicare-q&a.html>>

Another indication of the relative under-funding in research and development by the pharmaceutical industry is that a considerable proportion of the research funding for pharmaceutical companies comes from the public sector. A study in the United States, examining drugs developed between 1991 and 1997, found 30 new drugs classified as offering significant gains in therapy. Half of these were found to have been developed with public financial involvement at some stage of their research, and of those 15 drugs, 11 were financially funded through all of the stages of research.¹⁹ Furthermore, public funding is likely to be more critical where research is in areas of less certain commercial return. As Love and Nader state, “*The federal government plays a particularly important role in the highest risk research projects, including basic research, where commercial payoffs are least certain.*”²⁰

Despite these figures, the pharmaceutical industry claims that the research expenses are cumulative, arguing that it takes an average of 15 years to develop new medicines. It is estimated that any new drug will have cost the pharmaceutical companies anywhere from \$10 million USD up to \$500 million USD.²¹ However, a study by Tufts University and sponsored by PhRMA concluded that each new drug costs an average \$802 million USD.²² This study has been seriously criticised by consumer organisations and other health concern groups.²³ In particular, a study by Love and the Consumer Project on Technology (CPT) found that this figure is completely at odds with the information disclosed by pharmaceutical companies to the US tax authorities.²⁴ Something else that appears to be at odds with the research and development figures provided by the pharmaceutical industry is the fact that very few new chemical compounds are developed each year, in contrast with the considerable amount of pharmaceutical patents awarded. This is the concept of “ever-greening” already existing chemicals. Correa comments:

*The pharmaceutical industry significantly exploits incremental innovations through the development and patenting of a large number of improvements or minor changes on existing drugs, often in order to extend the effective term of protection for the original invention (“ever-greening”).*²⁵

Dutfield agrees with this point, and further comments that these practices establish “exclusion zones” that provide a competitive and bargaining advantage for patent owners.²⁶ The cumulative nature of the pharmaceutical market, coupled with other

¹⁹ Love, J. and Nader, R. *Federally Funded Pharmaceutical Inventions*. Testimony before the Special Committee on the Aging of the United States Senate, February 24, 1993. @: <<http://www.cptech.org/pharm/pryor.html>>

²⁰ Ibid.

²¹ DiMasi, J. A. "Trends in Drug Development Costs, Times, Risks", *Drug Information Journal*, 29 (2), 1995, pp.375-84.

²² Tufts Center for the Study of Drug Development. *Tufts Center for the Study of Drug Development Pega Cost of a New Prescription Medicine at \$802 Million*, November 30 2001. @: <<http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=6>>

²³ For a comprehensive list of some criticisms, see: <<http://rxpolicy.com/industry/802milliondollarquestion.htm>>

²⁴ Love, J. “CPTech release on Tufts study and IRS data”, *Ip-health List*, November 30, 2001. @: <<http://lists.essential.org/pipermail/ip-health/2001-November/002481.html>>

²⁵ Correa, C. “Internationalization of the Patent System and New Technologies”, *Conference on the International Patent System*, Geneva, Switzerland March 25 - 27, 2002. @: <<http://www.wipo.int/patent/agenda/en/meetings/2002/presentations/correa.pdf>>

²⁶ Dutfield, G. *Intellectual Property Rights and the Life Sciences Industries: A Twentieth Century History*, Aldershot: Ashgate, 2003, pp.109-110.

restrictive competitive practices, such as the existence of drug cartels,²⁷ serve to further undermine the argument that asserts the industry's pricing schemes and profits.

Another reason given by the pharmaceutical companies to support the pricing scheme is the Schumpeterian hypothesis, which roughly states that market power held by large corporations serves to stimulate innovations because the corporation is more capable of spending more on research and development. Indeed, R&D spending seems to rise more or less proportionally with a company's size after a certain level has been passed, but as Symeonidis points out, "*there seems to be little empirical support for the view that large firm size or high concentration are factors generally conducive to a higher level of innovative activity.*"²⁸ The figures presented earlier regarding the research spending by the pharmaceutical companies would seem to corroborate this observation.²⁹

Taking this into consideration, it is difficult to establish the reasons why the prices of pharmaceuticals remain as high as to maintain the substantial profits that have been described. Some argue that there is evidence that the pharmaceutical market is very similar to a monopolistic one because of the protection awarded by patents. Lall points out that "*the pricing policies of the large drug firms are based on purely monopolistic principles (...) rather than on the socially responsible one of lowering them after recovering research costs.*"³⁰ The common denominator seems to be the holding of a patent. Several studies cited by Reekie and Weber demonstrate that while a company holds a patent, the prices remain considerably high, and usually do not change whatsoever during the lifetime of the right. Prices only fall once the product is no longer under patent protection and can be manufactured by anybody else.³¹ This is the reason why the production of generic medicines – medicines that are not protected by patents – is a much more competitive and cheaper market. Grabowski points out that:

*...the development costs of generic compounds are relatively modest. In the United States, and most other countries, generic compounds must only show that they are bio-equivalent to the pioneering brand to receive market registration. This process only takes a few years and costs one to two million dollars.*³²

If generic medicines are cheaper to produce and result in a more competitive market, one should expect to see more generic production of pharmaceuticals after patents have expired. Unfortunately, this does not appear to be the case, as it would appear that generics are treated in many markets as separate products that require bureaucratic approval, making their implementation in a market much more difficult.³³ Others claim

²⁷ Ibid.

²⁸ Symeonidis, G. *Innovation firm size and market structure: Schumpeterian hypotheses and some new themes*. OECD Economics Department Working Paper No. 161, 1996. @: <[http://www.oilis.oecd.org/oilis/1996doc.nsf/LinkTo/OCDE-GD\(96\)58](http://www.oilis.oecd.org/oilis/1996doc.nsf/LinkTo/OCDE-GD(96)58)>

²⁹ For a comprehensive study of the pharmaceutical industry in the United States, see: Public Citizen's Congress Watch. *America's other Drug Problem: A briefing Book on the Rx Drug Debate*, Washington DC: Public Citizen's Publication Office, 2002.

³⁰ Lall, S. As cited by Reekie, W. D. and Weber, M. H. *Profits, Politics and Drugs*, London: MacMillan Press, 1979, p.94.

³¹ Reekie, and Weber, op cit; p.94-101.

³² Grabowski, H. "Patents, Innovation and Access to New Pharmaceuticals", *Journal of International Economic Law*, Vol.5, Issue 4, 2002, pp.849-860.

³³ For more on this, see: Griliches, Z. and Cockburn, I. "Generics and New Goods in Pharmaceutical Price Indexes", *American Economic Review*, Vol.84, Issue 5, 1994, pp.1213-1232.

that pharmaceutical companies dedicated to the production of generic drugs are often in direct competition with the innovation companies, and therefore making the generic market a much less profitable one because the proprietary industry has an advantage by their reliance in patented materials.³⁴ This indicates that patenting of medicines will continue because it is the most profitable development method.

1.2 Pricing out of reach

The existing proprietary system of pharmaceutical development based on patents has the end result of the existence of a market ruled by profits, with the price of even life-saving drugs determined by market forces. This has serious effects in the developing world. This situation means that drug prices remain too high for the most impoverished nations of the world. All around the developing world the evidence of the problem of drug pricing is evident. A report by Oxfam offers this example:

Two million children die every year from pneumonia, almost all of them in developing countries. US-based Pfizer's best-selling antibiotic, azithromycin (Zithromax), is particularly good for treating child pneumonia. It is under patent in Kenya, where it costs as much as in Norway. But Kenya only spends US\$17 per head every year on healthcare, while Norway spends US\$2300.³⁵

Drugs that are basic for the health in the developing world are at the moment unattainable. A study sponsored by the charity *Médecins Sans Frontières* (MSF) has found that several drugs required to treat common illnesses in the poorer countries are priced out of reach of the developing world. An example offered states that:

A recent study of bacterial meningitis caused by Streptococcus pneumoniae in children aged 2 months to 3 years demonstrated that use of ceftriaxone sodium could reduce mortality from 66% to 32% compared with treatment with chloramphenicol in oily suspension. Both antibiotics have a sustained action and require very simple protocols (daily intramuscular injection for a short time) and therefore are equally easy to use in adverse conditions. However, ceftriaxone treatment is 10 times more expensive than chloramphenicol.³⁶

This is important because acute respiratory infections kill almost 4 million people per year in the developing world, and as it has shown, ceftriaxone sodium is too expensive. The same situation can be found with diarrhoeal diseases, which kill 2.5 million people per year. A bacterial disease that has led to several outbreaks in developing countries is *shigella dysenteriae*, which has a mortality rate of 15% if left untreated. The strain of bacteria responsible has developed resistance to most antibiotics. The only ones that remain effective are fluoroquinolones such as ciprofloxacin and niprofloxacin, but these cost \$25 USD per dosage, instead of the \$2 USD for other regular antibiotics.³⁷

³⁴ US Congressional Budget Office. *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, Washington DC: U.S. Government Printing Office, 1998.

³⁵ Oxfam. *Priced out of Reach: How WTO patent policies will reduce access to medicines in the developing world.* @: <<http://www.oxfam.org.uk/policy/papers/priced/priced.html>>

³⁶ Chirac, P; Pécoul, B. et al. "Access to essential medicines in poor countries: a lost battle?" *JAMA*, Vol.281, No. 4, 1999, p.362.

³⁷ Ibid; p.363.

There also appears to be a severe drug pricing discrepancy between developed and developing countries. For example, Balasubramaniam points out that retail prices are often considerably higher in developing countries than in developed ones, with some countries experiencing prices that are four times higher than the recommended manufacturer price.³⁸ The reason for this seems to be an attempt by the pharmaceutical industry to maximise profits in economies that do not purchase their products in the same volume than developed nations. A spokesman of the British pharmaceutical industry expressed this by saying that “...*the reason multinational companies try to grab back as much profit as possible out of the less developed countries is frankly because they are suspicious of the future stability of their operations there.*”³⁹

The most worrying case of pricing medicines beyond reach, and perhaps the most publicised in the last years, is the case of the Acquired Immunodeficiency Syndrome (AIDS), caused by the Human Immunodeficiency Virus (HIV). By December 2001, an estimated 40 million people around the world carried HIV or have developed AIDS; 95% of those are in developing countries, and 30 million have died from the disease. Of those totals, 28.1 million people had been infected in Sub-Saharan Africa alone, with an estimate of 3.4 million added each year.⁴⁰ According to a joint study published by the WHO, UNICEF, UNAIDS and MSF, the high cost of HIV drugs is prohibitive for most of the countries in the developing world. The study has identified several reasons for the high cost of these medicines. According to the study, these are:

- *Patents*
- *Limited volume*
- *Limited price competition*
- *High import duties, tariffs, and local taxes*
- *High mark-ups for wholesaling, distribution, and dispensing*
- *Individual country pricing strategies—for example, price fixing by the government, policies of price freedom for new products or even agreements with industry on profit control.*⁴¹

According to the study, the price of a full treatment per person per year can range from \$10,000 to \$15,000 USD with medicines purchased in the developed world, depending on what type of treatment is taken.⁴² This is certainly beyond the budget of the countries that have been affected the most by the epidemic. The average per capita annual income for Africa is only \$510 USD, and in some affected countries like Burkina Faso, Mali, Nigeria and Madagascar, more than 65% of the population lives with less than \$1 USD a day.⁴³ Another report by the *Washington Post* calculates that, at current market drug prices, the cost of treating the entire population living with HIV/AIDS in Zimbabwe – one of the

³⁸ Balasubramaniam, K “Access to Medicines: Patents, Prices and Public Policy – Consumer Perspectives”, *Global Intellectual Property Rights*, Drahos and Mayne, op cit, pp.90-107.

³⁹ Teeling-Smith, G. As cited by Melrose, D. *Bitter Pills: Medicines and the Third World Poor*, Oxford: Oxfam Print Unit, 1982, p.27.

⁴⁰ More information and statistics on the epidemic can be found at the United Nations Programme on HIV/AIDS (UNAIDS) website at: <http://www.unaids.org/epidemic_update/report_dec01/>

⁴¹ UNICEF. *Sources and prices of selected drugs and diagnostics for people living with HIV/AIDS*. UNICEF, UNAIDS Secretariat, WHO and MSF Project, May 2002, p.1.

⁴² Chirac; Pécoul, Op cit.

⁴³ UNDP. *Population below income poverty line, 1983-99, 2001*.

most affected countries – would be \$18 billion USD, 265% of the Gross National Product (GNP) for that country. In contrast, the cost of treating all of the people infected in Switzerland is only \$144 million USD, as the infected population is only 12,000 people, representing only 0.06% of the country's GNP.⁴⁴

Geographical variations in prices of the same drug are also interesting to compare. GlaxoSmithKline's Retrovir costs £125 British Pounds (GBP) in the UK, but the same drug costs as little as £54 GBP if imported from other European countries. Another example is that *“in Brazil, the drug Fluconazole is available for US\$1, whereas in South Africa it costs US\$20. A 1998 study by the Consumer Project on Technology found prices for GlaxoSmithKline's version of Amoxil was \$8 in Pakistan, but was \$36 in Malaysia.”*⁴⁵

Another problem faced by the developing countries is that some drugs developed for combating tropical diseases are not being produced any more because they are no longer profitable. Some of these drugs were developed decades ago and are no longer subject to patents; however, they are not in use in the developed countries where those diseases are rare.⁴⁶ The problem is made more acute not only by the pricing scheme and lack of availability, but by the marked lack of research and development of drugs for diseases that affect the developing world. For example, a report in 1996 by the World Health Organization (WHO) says that *“of the \$56 billion spent on health-related research and development worldwide, only 0.2 percent is spent on pneumonia, diarrhoeal diseases and tuberculosis - which together represent 18 percent of the global disease burden.”*⁴⁷

Even countries with adequate levels of development can be hit suddenly when there is a disadvantageous economic shift. This is illustrated by the recent economic crisis in Argentina, which has been suffering one of the worse recessions in its history, with runaway inflation and a disastrous devaluation of the national currency. One of the many problems that have arisen for the Argentinean society is that suddenly people cannot afford medicines. This is illustrated by the fact that since the start of the crisis no insulin was available anywhere in the country, as the pharmacies, the government, and distributors could not afford to import it from abroad. The problem is that diabetics usually buy insulin supplies for about 120 days, but because of the devaluation, pharmacies are not accepting pre-orders, or giving credit. Any person who is ill has to be able to pay \$150 USD upfront, as the chemists are not accepting the national currency. This has reached such alarming stages that the Argentinean government had to declare a state of emergency and ask for insulin donations from abroad. The crisis is deepened by the fact that a total of 30% of the pharmacies in Argentina have had to close down. Hospitals are even finding it difficult to obtain even the most basic supplies, such as antibiotics, vaccines, gauze and needles.⁴⁸

2. Escaping the ownership stranglehold

Seeing how medicine prices affect health statistics, it should come as no surprise that many developing countries have been trying to get around the status quo and challenging

⁴⁴ Hirshcel, B. “The cost gap of fighting AIDS”, *The Washington Post Online*, 2000. @: <<http://www.washingtonpost.com/ac2/wp-dyn?pagename=article&node=&contentId=A58513-2000Dec28¬Found=true>>

⁴⁵ AVERT. *HIV and AIDS drugs in Africa*, 2001. @: <<http://www.avert.org/aidsdrugsafrika.htm>>

⁴⁶ Chirac; Pécoul, et al. Op cit.

⁴⁷ Deraj, R. “India caught in patent trap”, *Asia Times Online*, October 25, 2001. @: <<http://www.atimes.com/ind-pak/CJ25Df01.html>>

⁴⁸ Cañas, M. “Argentina se queda sin suministros médicos”, *Boletín Fármacos*, Volumen 5, número 1, enero 2002. @: <<http://www.boletinfarmacos.org/012002/noticias.htm>>

the international patent stranglehold in different ways, particularly by attempting to generate their own national pharmaceutical industries. Needless to say, the countries that have managed to achieve this are generally large developing countries, or countries with somewhat sophisticated R&D capabilities that enable them to imitate chemicals created in industrialised nations. The efforts of three developing countries to generate local pharmaceutical capabilities will be analysed next.

2.1. Costa Rica

Costa Rica is one of the first developing countries to adopt a social health policy, which included a program to provide affordable medicines to the poorest sectors of this Central American country. As a matter of fact, the country has been put forward as an example for a workable drugs policy that can have positive effects on health. As stated by Chetley: “*Can the products of the pharmaceutical industry help to improve health? Some of them can, as Costa Rica has shown through the judicious use of vaccines and a handful of other carefully selected medicines.*”⁴⁹

It was back in 1941 that the Costa Rican Congress approved legislation to create the *Caja Costarricense del Seguro Social* (CCSS), an autonomous government institution dedicated to manage the public healthcare system in Costa Rica. One of the first actions of the health system was to establish a public pharmacy in one of the main hospitals where patients would be able to obtain cheap medicines provided by the State.⁵⁰ The system of providing cheap or sponsored medicines continues to this day throughout the country, with several basic types of preventive medicine being awarded for free.⁵¹

Costa Rica has managed to ensure that the larger areas of the population have access to required medicines by following a double strategy. The first aspect of this strategy is to provide access to generic drugs either produced in the country or imported. These generic drugs are cheaper as they are produced without ties to patent licensing, which, as discussed, have the usual effect of making drugs more expensive. The second aspect is the importation of patented medications, but selling them at cheaper prices by providing a State funded subvention.⁵²

Access to generic drugs was not a problem with the existing patent legislations of the country, as it was deemed that there was an overriding necessity to provide access to basic medicaments to even the poorest sectors of the country. In particular, the patent legislation allows for two legal mechanisms that permit the State to use generic medication. One is by granting compulsory licensing (*licencia obligatoria*), which will take place when the patent owner has not made use of or licensed his invention. Any individual or company can then request that the State recognises a compulsory patent if it fulfils certain procedural requirements.⁵³ There is also an option for granting patents for public use, which means that the government can grant, by executive decree, a public licence for the exploitation of a patent by the State or any other parties specifically named in cases of public interest, emergency or national security. This would certainly include

⁴⁹ Chetley, Op cit.

⁵⁰ Miranda, G. *La Transición de la Nutrición y la Salud de Costa Rica Democrática*, Boston: International Foundation for Developing Countries (INFDC), 1996.

⁵¹ Miranda, Op cit.

⁵² United Nations Commission on Sustainable Development. *Aspectos sociales del desarrollo sostenible en Costa Rica*. April 1997. @: <<http://www.un.org/esa/agenda21/natlinfo/countr/costaric/social.htm#health>>

⁵³ *Ley No. 6867 de Patentes de invención, dibujos y modelos industriales y modelos de utilidad*. Costa Rica, Art. 18.

the patenting of medicines in case of public need. However, the State will grant compensation to the patent owner in case it decides to follow this procedure.⁵⁴

The existing regime has had a tremendous impact in the capabilities of the Costa Rican social health service to provide low cost medicines to the population. It is calculated that by 2002, the CCSS spent \$67 million USD in medicines from approximately 100 suppliers, and this figure makes up 80% of the entire Costa Rican pharmaceutical market.⁵⁵ It is calculated that this expenditure is particularly strong in generic drugs. The CCSS spends 33% of its budget to purchase medicines in patented or branded pharmaceuticals, while the remaining 67% goes to purchase generic medicines from generic suppliers.⁵⁶ The Costa Rican generic industry has been growing considerably, enhancing their imitation capabilities thanks to the acquiring power of the social health service. Of the four largest suppliers to the CCSS, three are the national generic companies Stein, Gutis and Raven, which provide 28.44% of the medicines purchased by the health service.⁵⁷ In total, the CCSS provides a total of 45 million doses of medicines per year.⁵⁸

The importance of generic drugs for the Costa Rican health service cannot be denied. For example, the price of the patented version of paclitaxel, a chemical used in the treatment of AIDS is \$160 USD per unit, while its generic equivalent costs \$25 USD, which has allowed decreasing the annual cost per person from \$6,800 USD to \$1,300 USD.⁵⁹

The mentioned provisions have made a remarkable difference in public health figures in Costa Rica. In 1940 the child mortality rate in the country was 123 per thousand births. In 1950, just nine years after the implementation of a social health system, this figure had come down to 90/1000. The figures continued to decrease steadily, until in 1970 the figure was 61/1000, and in 1980 it had decreased to levels comparable to those of developed countries at 19/1000.⁶⁰ Infant mortality under five in 2001 was 9/1000. Similar success can be seen in the life expectancy figures. In 1940, the life expectancy in the country was of 46.9 years. In 1950 the figure rose to 55.6 years, in 1970 it was 65.4, and in 2003 it is 77.9 years.⁶¹

It is difficult to measure the extent to which these figures can be attributed directly to the Costa Rican medicine policies, but there can be no doubt that wide access to some vital medicines – in particular antibiotics and vaccines – has played an important part in achieving these impressive advances in public health statistics. Nevertheless, it is important to point out that the Costa Rican improvement in these basic health figures is far better than the increases in the same data experienced on average around the developing world. In 1970, the average child mortality rate in the less developed countries was of 109/1000, and in 1999 it had been reduced to 59/1000. Life expectancy was 55 years in average, and in 1999 it had risen to 64 years.⁶²

⁵⁴ *Ley No. 6867*, Art. 20

⁵⁵ Avalós, A. “Guerra por calidad de medicinas genéricas”, *La Nación*, November 11, 2002.

⁵⁶ “Oposición médica defiende genéricos”, *El Nuevo Día* (Puerto Rico), February 11, 2004.

⁵⁷ Bermúdez Mora, K. “Medicamentos: Jaqueca del Cafta”, *El Financiero*, May 2, 2004.

⁵⁸ Avalós, A. “País defiende acceso a medicinas genéricas”, *La Nación*, October 10, 2003.

⁵⁹ “Oposición médica defiende genéricos”, op cit.

⁶⁰ Ministerio de la Presidencia de Costa Rica. *Indicators and democratic governance: Measuring Sustainable Human Development in Costa Rica*, 1998. @: <<http://www.estadonacion.or.cr/nacion2/indi-t2.htm>>

⁶¹ *Ibid.*

2.2 India

The case of India is very interesting for two reasons; India is one of the most populous countries in the world, and large sectors of its population live under exceptionally poor conditions. For the year 2003, India was ranked 127th in the Human Development Index, an appalling showing for a country with such high potential development.⁶³ Nevertheless, India has experienced some improvement in some basic statistics. For example, in 1973 more than half of the Indian population lived below the poverty line, which amounted to 54.9% of the total population. In 1999 the same figure had been reduced to 26.1%, a considerable improvement.⁶⁴

Before 1970, the state of the drug policy in India mirrored that of most of the developing world, with considerable reliance on the importation of medicines from developed countries. In fact, India produced locally only 25% of the total medicines consumed in the country.⁶⁵ It was in that year that India passed a new Patents Act. It has been argued that this Act has:

*...greatly weakened intellectual property protection in India, particularly for pharmaceutical innovations. Pharmaceutical product innovations, as well as those for food and agrochemicals, became unpatentable, allowing innovations patented elsewhere to be freely copied and marketed in India. The statutory term was shortened to 5 to 7 years on pharmaceutical process patents and automatic licensing was put in place.*⁶⁶

This legislation, disallowing the existence of product patents, had two different effects on the Indian pharmaceutical market. Firstly, local generic production of pharmaceuticals increased considerably; and secondly, foreign pharmaceutical companies decreased the amount of patents they had as they deemed that it was not worthwhile to manufacture under the existing legal conditions in the country. By 1991, Indian companies produced 70% of the drugs available in the national market.⁶⁷ The drug policy in India also emphasised some price control policies, with at least 74 different medicines protected by government pricing restrictions. The justification for this policy is to ensure wider access to and availability of essential drugs within the country.⁶⁸

These policies so far have been very successful in keeping prices down when compared to other countries. For example, the antacid drug ranitidine can be found in the West as the patented drug Zantac, but in India it is produced generically. The drug is 26 times more expensive in the UK than in India, and 56 times more expensive in the United States. The antibiotic ciprofloxacin is also produced generically in India, and it is up to 15 times cheaper than in the UK and the United States.⁶⁹ Another important achievement of the

⁶² World Bank. *Poverty Trends and Voices of the Poor: Social Indicators - Health: life expectancy, infant and maternal mortality, malnutrition.* @: <<http://www.worldbank.org/poverty/data/trends/mort.htm>>

⁶³ UNDP. *Human Development Index 2003*, Op cit.

⁶⁴ Bhalla, S. *FAQs on poverty in India*. Seminar at the Delhi School of Economics, July 20, 2000. @: <<http://www.oxusresearch.com/downloads/Ei200700.pdf>>

⁶⁵ Lanjouw, J. O. "The Introduction of Pharmaceutical Product Patents in India: Heartless Exploitation of the Poor and Suffering?" *Electronic Journal of Intellectual Property Rights*, Oxford IP Research Centre, WP 07/99, <<http://www.oiprc.ox.ac.uk/EJWP0799.html>>

⁶⁶ Ibid.

⁶⁷ Ibid.

⁶⁸ Ibid.

⁶⁹ Ibid.

Indian drugs policy is its potential for exporting cheap drugs to developing countries. For example:

Cipla, an Indian generic drug manufacturer, offered to supply triple-combination therapy for HIV/AIDS for \$350 per patient per year to Medicins San Frontieres. It also offered to sell the therapy for \$600 per patient per year to poor governments, on the condition that the recipient governments provide the drugs for free to those with HIV/AIDS.⁷⁰

Since the implementation of the 1970 Patent Act, various health indicators have improved. In 1970 the child mortality rate was 137.2 deaths per thousand births, and in the year 2001 it had fallen to 67/1000. The average life expectancy in 1970 was 49.4 years, and by the year 2001 it had increased to 63.3.⁷¹ This substantial improvement in health statistics cannot be attributed solely to the country's pharmaceutical policy, and it is impossible to measure just how effective the policy has been in providing cheap medicines, but there cannot be any doubt that wider access to drugs has been one of the factors that have allowed India to improve these figures. In the end, as expressed by Mira Shiva, an expert on pharmaceutical drugs with the Voluntary Health Association of India (VHAI), "*India's thriving drug industry has provided a good example of how drugs can be produced cheaply and profitably for local markets when unburdened by exorbitant licensing fees.*"⁷²

Despite serious challenges by developed countries – in particular the United States – and multinational pharmaceutical companies, India had been set to continue providing cheap access to drugs to its population. The government has repeatedly stated that among its main goals in the area of medicine there has to be a serious emphasis in attempting to provide cheap access to drugs, and to encourage research and development of new drugs by Indian companies.⁷³ However, the international pressure has finally produced some results and India is being forced to comply with international protection standards and to include in their legislation protection to product patents. Arguably, this is going to threaten the large generic market. Some reforms are on the way, but they are to be fewer than expected.⁷⁴

2.3 Brazil

Brazil is an oddity as far as developing countries goes, with a large population and impressive natural resources, yet with serious distribution problems. Brazil's economy is plagued by inequality, corruption, high inflation and devaluation. In the year 2001, Brazil was considered a medium development country by the UNDP, being placed 69th in the Human Development Index.

Brazil was one of the original signatories of the Paris Convention for the Protection of Industrial Patents, and ratified the agreement in July 7, 1884. As such it has been part of the international patent protection system, although in a lax manner. The modern Brazilian pharmaceutical policy dates back to the implementation of the 1971 Code of

⁷⁰ Consumer Project on Technology. *Offers of Price Reductions for HIV/AIDS Drugs*, 2001. @: <<http://www.cptech.org/ip/health/pcuts.html>>

⁷¹ UNDP. *Human Development Index 2003*, op cit.

⁷² Deraj, Op cit.

⁷³ Indian Department of Science and Technology. *Pharmaceutical Policy 2002*. @: <<http://www.technopreneur.net/timeis/cgovt/pharmapolicy.html>>

⁷⁴ "India reforms drug patent laws", *BBC News*, 15 May, 2002. @: <<http://news.bbc.co.uk/1/hi/business/1988867.stm>>

Industrial Property, which covered everything relating to patents. Although this legislation complied with most of the prior recommendations set by the Paris Agreement, it made two very important exceptions, as pharmaceuticals and food were not covered by either product or process patent system.⁷⁵ This meant that the national pharmaceutical industry could produce cheap versions of patented drugs and make them available to the local market.

Besides the specific exception to pharmaceuticals, the Brazilian legislation was able to provide several other provisions to safeguard the widest possible access to medicines to its population by means of many other legal mechanisms, such as a comprehensive system of compulsory licensing. The Brazilian legislation required a patent owner to work or effectively exploit a patent in the country; merely importing a patented product into Brazil did not constitute effective exploitation of the patent. This meant that any interested party could, with very little effort, claim that a patent was not being exploited, thus being granted a compulsory licence.⁷⁶ The government could also grant compulsory licences in cases of public interest, but this would be a non-exclusive right and could be exploited by any other interested party, the rationale behind this being cases of national security or health.⁷⁷

A new patent legislation was passed in 1996, with the main change that it allowed for the patenting of pharmaceuticals, but retained the provisions on compulsory licensing due to disuse or for public interest.⁷⁸ In those respects, Brazilian law does not differ much from the provisions that can be found in other developing countries, such as the mentioned cases of India and Costa Rica.

Perhaps one of the most interesting features of the Brazilian legislation is that it specifically allows for the existence of parallel imports. Article 68(3) and (4) of the Brazilian patents legislation allows for the existence of parallel imports into the Brazilian market. The article states “*In case of importation, in order to exploit a patent or importation in the preceding paragraph, third parties shall also be allowed to import a product manufactured according to a process patent or a product patent, provided it has been placed on the market directly by the patent owner or with his consent.*”⁷⁹ This means that if a pharmaceutical is made available in a market, then Brazil can import it from that market with no legal complications.

To complement the compulsory licensing and parallel imports provisions in Brazil, there is legislation that specifically allows the country to produce its own generic version of patented drugs. The legal framework for this was initially set by executive decree number 793 of April 5 1993, which allows for generic drugs to be produced by authorised manufacturers in accordance with the compulsory licensing provisions described, and established a system of registration for such pharmaceuticals. The system was later made into law in 1999.⁸⁰

With the legal framework in place, the Brazilian government started to encourage the production of several drugs in the country, with the main efforts being directed towards

⁷⁵ Shanker, D. “Brazil, the Pharmaceutical Industry and the WTO”, *Journal of World Intellectual Property*, Vol.5 No.1, January 2002, p.58.

⁷⁶ *Law No. 5722, Code of Industrial Property 1970*. Brazil, Arts. 33 and 49.

⁷⁷ Shanker, Op cit; p.58.

⁷⁸ *Ibid*; p.54.

⁷⁹ *Law No. 5722, Code of Industrial Property 1970*, Brazil, Art. 68(4).

⁸⁰ *Lei No. 9787, Medicamentos genéricos*, 1999, Brazil.

producing medicines to treat HIV/AIDS, which poses a large health concern. Brazil has the largest population infected with HIV in Latin America, with an estimated 540,000 people living with HIV/AIDS in 1999.⁸¹ Soon after, Brazilian pharmaceutical companies sponsored by the government were producing several anti-retrovirals and other medicines to decrease the effects of the disease, including very expensive patented drugs such as nevirapine, AZT and 3TC. With the use of these generic drugs, the price of a complete treatment has been drastically reduced when compared to countries with patented medicines, averaging \$1.55 USD per day – as opposed to an average \$40 USD a day in developed nations. Brazil also provides a cocktail of 12 different drugs for free to more than 100,000 people who cannot afford them.⁸² There are many indications that point towards the success of the Brazilian generic HIV drugs policy. The number of deaths caused by AIDS has been reduced by up to 50% since 1996, and 146,000 patients have avoided hospitalisation since 1997.⁸³

Just as with the other countries mentioned, the open pharmaceutical policy in Brazil has been translated in gradual increase in health statistics. In 1970 infant mortality was 96/1000 births, and the life expectancy was of 59 years. In 2001 the infant mortality stood at 36.96/1000 births, and life expectancy had risen to 67 years.⁸⁴

3. The Empire strikes back

As shown in the previous section, some countries have started to take steps to provide large parts of their populations with basic medicines, but the pharmaceutical multinational companies did not take these efforts lightly. Making use of the impressive political and economic power that they possess, some of these companies started to act against some of the countries that they believed did not provide adequate protection for their patented products.

The strategy of the pharmaceutical industry appears to be clear. The industry is using the political influence they have in the United States to try to get the American government to send a message to some developed nations by threatening them with trade sanctions through the aforementioned Special 301 status.

An example of a country that is suffering such the threat of the trade sanctions India, which has been named as a Priority Foreign Country by the USTR in the last four years, mostly because of its generic pharmaceutical policies. PhRMA is setting its sights on India by continually requesting that they be placed on the list. In their latest recommendations to the US government, they complain that:

⁸¹ Central Intelligence Agency. *CIA fact book: Brazil*. @: <<http://www.cia.gov/cia/publications/factbook/geos/br.html>>

⁸² Associated Press. *Brazil Denies Exporting AIDS Drugs To South Africa*, January 30, 2002. @: <<http://www.aegis.com/news/ap/2002/AP020132.html>>

⁸³ International Gay and Lesbian Human Rights Commission (IGLHRC). *Interests that Kill: US Pressures Brazil to Abandon Successful AIDS Program*. @: <<http://www.iglhrc.org/site/iglhrc/>>

⁸⁴ Schmidt, A. *A demographic profile of Brazil*. Population Resource Center Report, September 1999. @: <<http://www.prcdc.org/summaries/brazil/brazil.html>>

*The damage caused by the inadequate protection of intellectual property rights in India reaches beyond direct losses caused by displaced sales in India. Indian bulk pharmaceutical companies aggressively export their products to third countries where intellectual property laws are similarly lax. The damage caused to U.S. pharmaceutical manufacturers due to the deficiencies of the Indian patent regime thus goes beyond displaced sales in the Indian market, and reaches to the ability of U.S. companies to compete in other significant markets, especially in the Asia-Pacific and Middle East regions.*⁸⁵

The United States has already taken India to the WTO arbitration procedures in 1998, and they won when the WTO appellate body found that Indian pharmaceutical provisions described earlier contravened India's responsibilities within the WTO.⁸⁶

The second strategy is to place court cases in other countries to get some legislation repealed. The third and less obvious strategy is to mount a public relations campaign to gain public support to the above-mentioned policies, getting into a rhetorical game of blaming the victim. To them the problem is not that drugs are too expensive and cannot be afforded by the less developed countries, the problem is that those countries have too many internal problems and cannot provide for their own citizens adequately. As stated in one of the web sites run by the industry advocate PhRMA, "*Criticisms of drug patents deflect attention from the real barriers to health care — poverty, inadequate infrastructure, flawed health systems, cultural barriers and political corruption.*"⁸⁷ This shifts the blame of the problem on the affected countries themselves and the corruption they face. Corruption is indeed a real threat and must not be under-estimated. Responding to public outrages, some pharmaceutical companies started sending drugs to African countries as humanitarian aid. A worrying recent report informs that a large shipment of anti-retroviral drugs produced by GlaxoSmithKline intended for the Ivory Coast, Senegal, Togo and the Republic of Congo were seized by corrupt officials and sent back to Europe to be resold. The culprits of this outrage appear to be officials in the receiving ports, and similarly corrupt Western traders.⁸⁸ It is extremely worrying that such negative experiences may hinder future efforts to provide assistance to AIDS ravaged nations.

3.1 The case against Brazil

Because of the amount of political power held by the pharmaceutical industry in the United States, as examined earlier, there has been a marked effort by the representatives of the industry to request trade sanctions against several countries.

The United States trade legislation that allows the legal imposition of trade sanctions against countries that do not protect intellectual property becomes particularly relevant in this case. As discussed above, every year the pharmaceutical industry watchdog in the United States writes a report about the countries that should be awarded with Special 301 status, and lists others that should be watched. For the last four years, PhRMA has been

⁸⁵ PhRMA. *Special Submission: Priority Foreign Country 2001*, Op cit.

⁸⁶ Brown, E. "TRIPS: India - Patent Protection for Pharmaceutical and Agricultural Chemical Products Introduction", *European Journal of International Law*, Vol.9, No. 1, 1998 p.182-184.

⁸⁷ PhRMA. *Health Care in the Developing World: Intellectual Property and Access to AIDS Drugs*. 2002. @: <<http://world.phrma.org/ip.access.aids.drugs.html>>

⁸⁸ Boseley, S and Carroll, R. "Profiteers resell Africa's cheap Aids drugs", *The Guardian*, Friday October 4, 2002. @: <<http://www.guardian.co.uk/aids/story/0,7369,804387,00.html>>

complaining about Brazil, recommending that it should be included in the “Priority Watch List”.⁸⁹

For the year 2001, PhRMA complained about two different situations in Brazil that affected their share of the market. The main complaint concerned the regulations described in the previous section in regards to compulsory licences and the granting of powers to create generic versions of patented medicines. PhRMA claimed these powers contravene regulations in the TRIPS agreement. The other complaint referred to temporary measures implemented by the Brazilian government in 1999. Due to the serious economic crisis in Brazil, the government adopted a series of temporary measures that have frozen drugs prices by only allowing an increase of 4.4% in prices in comparison with the previous year. This is way below devaluation and inflation rates.⁹⁰

The complaints against Brazil should come as no surprise, as the country has the largest potential market in South America, for the pharmaceutical industry. Multinational corporations made a total of \$7.2 billion USD in 1998, which dropped to \$5.3 billion USD in 1999 and \$5.5 billion USD in the year 2000, mostly due to the economic crisis in the country and the marked increase in the generic drugs market.⁹¹ The potential share of such a market by the pharmaceutical companies is such that the United States decided to stage a trade dispute in April 2000 at the WTO against the Brazilian patent regulations that allow parallel imports and compulsory licensing, requesting that the WTO set up a panel to investigate these issues.⁹²

The arguments put forward in this case were simple. The United States pointed out that Article 68 (1)(i) allowed for compulsory licences to be established in the case where the patent had not been exploited in Brazil three years after the patent was issued. This, according to the United States, was in breach of Article 27.1 of the TRIPS agreement, which states that “*patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.*”⁹³ The use of this article by the United States would appear erroneous, as what the Brazilian legislation is doing is not to create a discrimination against the patent, but to establish certain limits if the patent is not properly worked locally. This is perfectly accepted by other patent agreements, such as the Paris Convention for the Protection of Industrial Property. In particular, Art. 5(A)(4) clearly states that:

*A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons.*⁹⁴

It is clear that by reading both treaties, the Brazilian legislation does not violate international patent protection provisions, and the argument has no merit.

⁸⁹ PhRMA. *Special Submission: Priority Foreign Country 2001*. 20 February, 2001. @: <<http://www.phrma.org/intnatl/news/2001-02-20.40.pdf>>

⁹⁰ Ibid.

⁹¹ Ibid.

⁹² Shanker, op cit; pp.53-55.

⁹³ TRIPS, Art. 27.1.

⁹⁴ Paris Convention for the Protection of Industrial Property, Art. 5(A)(4).

The case produced considerable protest from NGOs and AIDS activists, as it was deemed that the action had been taken against the Brazilians to set them up as an example to other countries because they had been producing generic AIDS medicines.⁹⁵ Despite this, it is important to note that the United States denies that this dispute is about the generic medicines, stating that it was only against the compulsory licensing and parallel import provisions of the Brazilian patent legislation. In a letter by an American trade representative to an AIDS advocate group, it is stated that “*this dispute is not about health or access to drugs. It is about a measure that discriminates against imported products in favor of locally produced products, regardless of whether these products are health-related or not.*”⁹⁶

The United States abandoned this dispute in June 2001.⁹⁷ The reasons for this are unclear; it may be a combination of factors. Maybe this was a response to the international outrage and the accusations of bullying by an economic power to a country attempting to fight AIDS, and maybe even a realisation that the case was not strong to begin with. What is evident is that the action was initiated as the direct result of the pressure exerted by the pharmaceutical industry, and in particular by the influential writings of PhRMA. Indeed, Shanker points out that several official studies from the American government are influenced by the drugs industry, stating that in those studies “*practically every piece of information pertaining to U.S. pharmaceutical companies was taken from PhRMA’s publications.*”⁹⁸

3.2 The case against South Africa

The case of South Africa has become one of the most publicised in recent years due to the HIV/AIDS epidemic in Africa. In South Africa alone, the situation is dire; from a population of 40 million, it is believed that 4.5 million people have been infected. This translates to more than 10% of the total population, and almost 20% of those aged 15-49, being the country with the largest living infected inhabitants in the entire world.⁹⁹

This is a heavy toll for a developing country, more so when the high prices for retroviral medicines used to treat the symptoms are taken into consideration. South Africa is ranked 111th place in the 2003 HDI, and although some of their statistics are not as worrying as many other Sub-Saharan African countries, health is certainly an issue. The per capita income for South Africa is \$11,290 USD per year, with a life expectancy of 53.7 years and an under-five infant mortality rate of 71/1000 births. One of the main causes for these worrying figures is the AIDS epidemic. With so many health problems, it is doubly worrying to point out that the per capita health expenditure is \$663 USD per year, with the public percentage expenditure in relation to the Gross Domestic Product of only 3.7%.¹⁰⁰

⁹⁵ For an example of such anger, see: Oxfam. *Drug Companies vs. Brazil: The Threat to Public Health*. Oxfam GB Briefing Paper, May 2001. @: <<http://www.oxfam.org.uk/policy/papers/brazilctc/ctcbraz.htm>>

⁹⁶ Gonsalves, G. “Brazil/WTO case: USTR Response”, *E-Drug e-mail Distribution list*. Communication from Joseph Papovich, Assistant United States Trade Representative, posted by recipient, 21 February, 2001.

⁹⁷ USTR. *United States and Brazil agree to use newly created Consultative Mechanism to promote cooperation on HIV/AIDS and address WTO patent dispute*. Press release, June 25, 2001. @: <<http://www.ustr.gov/releases/2001/06/01-46.pdf>>

⁹⁸ Shanker, op cit; p.95.

⁹⁹ Washington Post Online. *Special report on AIDS in Africa*. @: <<http://www.washingtonpost.com/wp-dyn/world/issues/aidsinafrica/>>

¹⁰⁰ United Nations Development Program. *South African HDI indicators 2003*. @: <http://hdr.undp.org/reports/global/2003/indicator/cty_f_ZAF.html>

Faced with such an epidemic and lack of resources to deal with it properly, South Africa started to look for cheaper sources of supply for anti-retroviral pharmaceuticals to try to alleviate the problem. The 1978 Patent Act already allowed for compulsory licensing in the cases of abuse of the patent owner's rights, not dissimilar to the provisions already in existence in other developing countries.¹⁰¹ However, the conditions for the granting of a compulsory licence were very narrow, such as in cases of disuse, abuse or the refusal to grant a patent. Nevertheless, it is important to note that the Act allowed also for the granting of a compulsory licence if "*the demand in the Republic for the patented article is being met by importation and the price charged by the patentee, his licensee or agent for the patented article is excessive in relation to the price charged therefore in countries where the patented article is manufactured by or under licence from the patentee or his predecessor or successor in title.*"¹⁰² This would seem to open the door for granting patents in case a product was being offered at a higher price in South Africa than in the country of origin, but it is still rather restrictive in the amount of cases in which such licences could be granted. Another problem present in the Patent Act was that it did not allow for compulsory licensing in cases of public interest, as is the case in other of the studied cases.

As the existing system limited the options that could be taken, the South African government attempted to address the crisis by passing a new regulation in 1997. This new legislation gave wider powers to the Department of Health to make exceptions to the existing patent law in cases of health emergencies facing the country, in the form of the Medicines and Related Substances Control Amendment Act. Among the many provisions of the new legislation, the most important appear to be those that allow for parallel imports of patented and generic pharmaceuticals into South Africa in an effort to ensure access by the public to more affordable medicines. The most controversial article of the Act states that:

The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may-

- (a) notwithstanding anything to the contrary [...], determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;*
- (b) prescribe the conditions on which any medicine [...] may be imported.*¹⁰³

This opened the door for both parallel imports and generic imports of medicines, which was not possible with earlier legislation. With the legal framework in place, South Africa started importing small quantities of cheap anti-retroviral drugs from Brazil,¹⁰⁴ but the country is still suffering from a serious lack of access to these drugs.

Even before the implementation of the new patent provisions, representatives from pharmaceutical companies and the United States government made several comments to the South African government and the press warning them that the provisions included in

¹⁰¹ *Patents Act 1978, South Africa*, Arts. 55 and 56. @: <<http://www.gpa.co.za/english/za/pact.htm>>

¹⁰² *Patents Act 1978, South Africa*, Art. 56 s.2(e).

¹⁰³ *Medicines and Related Substances Control Amendment Act 1997, South Africa*. @: <<http://www.polity.org.za/govdocs/legislation/1997/act90.pdf>>

¹⁰⁴ Associated Press. *Brazil Denies Exporting AIDS Drugs To South Africa*. Op cit.

the new legislation went against international treaties on patent protection.¹⁰⁵ These warning went unheeded and the Act was passed and signed by then president Nelson Mandela in November 1998, and was scheduled to enter into effect in April 1999.

Because of the implementation of the new Act, 42 pharmaceutical companies brought a case to the South African High Court on February 1999, requesting that the provisions regarding compulsory licensing, parallel imports and the special powers granted to health authorities to circumvent patent legislation in cases of public interest, should be invalidated.¹⁰⁶

One of the first requests of the action was that the court should issue an injunction stopping the new legislation from coming into effect. This was granted by the Court, leaving the provisions on stand-by until the court case was solved. The claimants also requested that the case should be referred to the Constitutional Court for analysis of the alleged unconstitutionality of several parts of the new law. Although claims were brought against several of the articles of the 1998 Act, the main target was Article 15c, which has been described already. The reasons for requesting invalidation on the grounds of unconstitutionality were as follows:

- a) The article did not set any policy guidelines for the declaration of making drugs more accessible to the public.
- b) The proposed changes give the Minister of Health powers to restrict the scope of existing patent rights in South Africa.
- c) The article allows the South African government to deprive intellectual property right holders without specifying rules for compensation.
- d) The provisions in the article go against the Article 27 of the TRIPS agreement, which is a ratified treaty by the Republic of South Africa.

The response by the South African government was that parallel imports were not specifically forbidden by the TRIPS agreement, and that the provisions in the new Act were not unconstitutional. The defendants conceded the point regarding compulsory licensing, arguing that the article in question would not be used for that purpose, but only for parallel import, arguably because the legal team representing the government thought that this concession would give them a better chance of winning the case.¹⁰⁷

On September 8, 1999, the High Court remitted the case to the Constitutional Court as requested. Instead of entering into analysis of the validity of the unconstitutional claims made by the pharmaceutical companies, the Court first ruled on other claims of irregularities regarding the implementation of the Act (scheduled for April of that year). The Court was asked if such implementation would be legal under the Constitution, as the South African legislative body had not yet passed several procedural mechanisms that should accompany the Act.¹⁰⁸ On these procedural requirements, the Court eventually ruled that the previous legislation on the control of medicines would stay in place until the

¹⁰⁵ Among these were letters from PhRMA representatives, the USTR and the American embassy in Pretoria. See: Consumer Project on Technology. *Time-line of Disputes over Compulsory Licensing and Parallel Importation in South Africa*. August 5, 1999. @: <<http://www.cptech.org/ip/health/sa/sa-timeline.txt>>

¹⁰⁶ *Pharmaceutical Manufacturers Association of SA and Another: In re Ex parte President of the Republic of South Africa and Others*. 1999 (4) SA 788 (T). @: <<http://www.cptech.org/ip/health/sa/pharmasuit.html>>

¹⁰⁷ Love, J. *Report on court case over South Africa Medicines Act*, March 5, 2001. @: <<http://www.hivnet.ch:8000/topics/treatment-access/viewR?949>>

¹⁰⁸ *Pharmaceutical Manufacturers Association of SA and another In re: the ex parte application of the President of the Republic of South Africa and others*. Constitutional Court - CCT31/99, 2000 (2) SA 674 (CC); 2000 (3) BCLR 241 (CC). 25 February 2000. @: <<http://www.concourt.gov.za/judgments/2000/pharm.pdf>>

President determined a date for bringing the new Act into force.¹⁰⁹ This was the first blow to the pharmaceutical companies.

The Court held hearings between March 4 and 6, 2001, where both sides presented their cases, and several affidavits and amici curiae were also read. On the final day of proceedings, the claimants presented a request for recess, which the Court accepted. This was the last legal action the Court would hear from this case.

From the start of the legal dispute, the case had been receiving a large amount of media attention. This publicity was not complimentary to the pharmaceutical companies; the lawsuit seemed like a straightforward case of corporate greed against a country crippled by the scourge of the AIDS epidemic. The common denominator in many of the articles seemed to be that the pharmaceutical companies were putting profits before human lives, an instant headline grabber.¹¹⁰

At the same time, NGOs, AIDS charities, anti-globalisation activists and many other pressure groups took the side of South Africa and started campaigning hard against the lawsuit.¹¹¹ The pharmaceutical companies found themselves fighting a lonely war on the battlefield of public opinion, an engagement that they seemed doomed to lose.

In the end the public pressure won. It is entirely possible that the industry considered that such bad press might be detrimental for future cases in which they would try to protect their intellectual property rights. It could also be that an increase in bad press in the developed world, in particular in Europe and the United States, may have worried some companies about losing political influence, or even a backlash that could result in stricter price regulation, something they have thoroughly opposed in the past.

The fact is that on April 19, 2001, the pharmaceutical companies abandoned their case and settled with the South African government. The terms of the settlement were described as beneficial to all parties by several observers, and were welcomed with almost universal approval around the world. In the end, the pharmaceutical industry could claim that the South African government agreed to hold talks with their representatives regarding the future implementation of the new Medicines Act. The South African government obtained assurances that the pharmaceutical companies would not pursue the matter and would be understanding of the South African AIDS situation. The statement says:

*The government of the Republic of South Africa reiterates its commitment to honour its international obligations including the Agreement of Trade Related Aspects of Intellectual Property Rights (TRIPS). In reliance of this commitment, the referenced applicants recognize and reaffirm that the Republic of South Africa may enact national laws or regulations, including regulations implementing Act 90 of 1997 or adopt measures necessary to protect public health, and broaden access to medicines in accordance with the South African Constitution and TRIPS.*¹¹²

¹⁰⁹ Ibid.

¹¹⁰ For example, see: Mathiason, N. "South Africa fights Aids drug apartheid", *The Observer*, January 14, 2001. @: <<http://www.observer.co.uk/business/story/0,6903,421887,00.html>>

¹¹¹ Pressure groups included support from groups like UNAIDS, MSF, Oxfam, Amnesty International, Human Rights Worldwide and many others. For an example of the support gathered by the movement, see: ACT UP, the Grey Panthers, the Health GAP Coalition, Oxfam America, and Doctors Without Borders. *Solidarity with South Africa on the 1997 Medicines Act*, March 12, 2001. @: <<http://www.cptech.org/ip/health/sa/SAsolidarity.html>>

¹¹² "Aids court battle: Joint statement", *BBC News*, 19 April, 2001. @: <http://news.bbc.co.uk/1/hi/english/world/africa/newsid_1285000/1285645.stm>

Although the drug companies claimed a partial victory, it seems obvious that the victory was really for the South African government, as there was a direct recognition that the articles in question could remain as they were. Because of that reason, this settlement has been welcomed and reported as a victory for the developing world against multinational corporations.

3.3 TRIPS-plus

Since the year 2000, the United States has been pursuing another strategy with regards to international trade that has severe implications for the access to medicines debate. The United States has been signing bilateral or multilateral agreements with developing countries in which the US agrees to provide trade benefits or assistance to a developing country; with the condition that they sign up to different sets of trade-related clauses that are designed to protect American interests in the signing country.¹¹³ Included in these agreements, there are several clauses relating to intellectual property rights that provide obligations that go beyond those enshrined in the TRIPS agreement. This has prompted some commentators to define these agreements as “TRIPS-plus”.¹¹⁴

The content of the TRIPS-plus agreements vary, but of interest to the issue of access to medicines are those provisions regarding patents. TRIPS-plus bilateral agreements enhance the protection awarded by TRIPS through two mechanisms, particularly the prescription of longer patent protection and the imposition of severe restriction to the grounds for granting compulsory licences.¹¹⁵ The implementation of the bilateral agreements has been boosted by the passing by the US Congress of the Bipartisan Trade Promotion Authority Act 2002, which makes it easier for the USTR to negotiate and conclude these agreements.¹¹⁶ A result of the political will and commercial lobbying pushing the TRIPS-plus agreements forward, there are a growing number of countries that have entered and concluded such negotiations.¹¹⁷

An example of a bilateral TRIPS-plus agreement is the signing of the U.S.-Chile Free Trade Agreement, which contains a provision that practically destroys the existence of compulsory licensing in that South American country.¹¹⁸ Of particular interest is Art. 17.9. This article contains provisions that erode rights existing in TRIPS and other international agreements, including the following:

- Patent terms can be extended to compensate for administrative delays.

¹¹³ Maskus, K. and Reichman, J. “The Globalisation Of Private Knowledge Goods And The Privatisation Of Global Public Goods”, *Journal of International Economic Law*, Vol.7, No. 2, 2004, p.279-320.

¹¹⁴ Vaver, D. “Invention In Patent Law: A Review And A Modest Proposal”, *International Journal of Law and Information Technology*, Vol.11, No.3, 2003, pp.286-307.

¹¹⁵ Rivas Campo J.A. and Juk Benke, R.T. “FTAA Negotiations: Short Overview”, *Journal of International Economic Law*, Vol.6, No. 3 2003, pp. 661-694.

¹¹⁶ Bagley, M. “Legal Movements in IP: TRIPS, Bilateral Agreements, and Access to Essential Medicines”, *Emory International Law Review*, Vol.17, 2003, p.781.

¹¹⁷ At the moment of writing, the United States had signed TRIPS-plus bilateral agreements with Jordan, Laos, Chile, Singapore and Israel. Several other countries are conducting bilateral negotiations with Bahrain, Morocco and Vietnam. Updated information can be found here: <<http://www.tcc.mac.doc.gov>>

¹¹⁸ Office of the United States Trade Representative. *Summary of the U.S.- Chile Free Trade Agreement*, 2002. @: <http://www.ustr.gov/regions/whemisphere/samerica/2002-12-11-chile_summary.pdf>

- Chile can legislate exceptions to the normal rights granted by a patent, but these exceptions “do not unreasonably conflict with a normal exploitation of the patent”.¹¹⁹
- The grounds for revoking a patent are limited to the same grounds required originally to refuse a patent, eliminating the ground of non-use.
- Chile can grant the use of the "subject matter" to a third party only for the purpose of making an application for "marketing approval or sanitary permit of a pharmaceutical product."¹²⁰

All of the above constitute a de facto erosion of compulsory licensing, as it is difficult to see how a licence could be granted without contravening the above provisions.

A more efficient strategy has been to negotiate multilateral agreements with blocs of countries, as it allows for multilateral negotiations that will allow the United States to implement some of the enhanced patent protection to a larger number of countries.¹²¹ One of the most worrying cases of such multilateral agreements can be found with the Andean region countries (Colombia, Ecuador, Peru and Bolivia), where the United States suggested a series of measures that these countries had to undertake in order to be able to receive monetary assistance for the fight against drug traffickers and leftist guerrillas.¹²² These countries entered into a trade agreement with the US named the Andean Trade Promotion and Drug Eradication Act (ATPDEA)¹²³ in order to receive the funds and to be able to obtain preferential trade treatment. The agreement included a clause that would eliminate the practice of providing protection to generic drugs, ensuring that drugs would receive a minimum period of protection of five years before being marketed as generic. The US is also negotiated with numerous other developing countries in Latin America. Very tough rules on IPRs are being included in the draft text for the Free Trade Area of the Americas (FTAA), where Section 5.5 of the Draft Chapter on IP Rights contains serious constraints to compulsory licensing.¹²⁴

The largest and most controversial multilateral agreement signed to date is the Central American Free Trade Agreement (CAFTA) in early 2004.¹²⁵ CAFTA has been surrounded by controversy because it appears to be a precursor of the tactics and provisions that will be pushed in the FTAA. Intellectual property plays a large role in the negotiation of such agreements, and from the beginning of the negotiations, representatives from Central American developing countries were warned that IPRs would be one of the most difficult negotiating points of the agreement, as it was at the top of the American agenda.¹²⁶ CAFTA follows closely the wording of the U.S.-Chile Free Trade Agreement with regards to patents, and most of the provisions have been kept after

¹¹⁹ United States/Chile Free Trade Agreement, Art. 17.9 para 3.

¹²⁰ Ibid.

¹²¹ These include proposals to create multilateral agreements with the Middle East, and with the Southern African Customs Union (SACU).

¹²² Vélez Castaño, M. “Un vuelco en medicamentos” *El Colombiano*, September 20, 20002. @: <<http://www.elcolombiano.terra.com.co>>

¹²³ Office of the United States Trade Representative. *First Report to the Congress on the Operation of the Andean Trade Preference Act*, April 30, 2003. @: <<http://www.ustr.gov/reports/2003atpa.pdf>>

¹²⁴ MSF. *US Trade Measures Threaten Access to Medicines in Latin America and the Caribbean*, 31 October, 2002. @: <<http://www.accessmed-msf.org/prod/publications.asp?scentid=31102002954482&contenttype=PARA&>>

¹²⁵ The text of CAFTA can be found here: <<http://www.ustr.gov/new/fta/cafta.htm>>

¹²⁶ Communication with Ms. Margarita Umaña, member of the CAFTA negotiation party for Costa Rica.

signing. This translates to an enhancement of patent protection that erodes the circumstances in which compulsory licences can be granted. However, there are a couple of encouraging improvements that have been negotiated into the agreement, particularly from the initial refusal from Costa Rica to sign the agreement as it was and by walking out of the negotiations.¹²⁷ One of the main changes from the text of the Chilean FTA is that CAFTA adds one paragraph to the reasons by which a patent could be struck down. The paragraph says that “*fraud, misrepresentation, or inequitable conduct may be the basis for revoking, cancelling, or holding a patent unenforceable.*”¹²⁸ Of interest is the use of “inequitable conduct”. This could be used by courts to cancel patents in which the holder may refuse to commercialise the product in the country.

What is going to be the effect of CAFTA to the issue of access to medicines? Even as early as the negotiating stages, commentators had expressed serious concerns about the effect that CAFTA would have for the Costa Rican health system. Professional and industry associations, such as the Medical Association and pharmaceutical industry representatives, publicly expressed that CAFTA would restrict the use of generic medicines.¹²⁹ The figures seem to back up such concerns. In 2003 the CCSS had purchased 63 patented medicines at a cost of \$23 million USD, while 373 generic medicines had cost \$47 million USD.¹³⁰ Representatives from Costa Rican health services expressed concern that any change in the current balance would have tremendous effects to the Costa Rican social health programmes. For example, if the CCSS has to purchase licences for the use of one widely used medicine such as enapril, this would mean an increase in \$12 million USD per year.¹³¹ Others have expressed that a substantial reduction in the number of generic medicines purchased by Costa Rica would have nefarious effects to the amount of coverage from the public health system. At present, Costa Rica boasts that it can provide total coverage of the pharmaceutical needs of the poorest sectors of the population, but an increase in costs due to expenditure in patented medicines would mean that the CCSS could only cover 19% of the poorest inhabitants.¹³²

4. Doha and beyond

4.1 The Doha process

During the 2001 WTO Doha Ministerial Meeting, the participants became aware that health and the access to medicines debate were of extreme importance for developing countries. This is the reason why the meeting produced a separate document regarding health, the Declaration on the TRIPS Agreement and Public Health, a document that tries to enforce the importance of health to the international community. The Declaration starts by commenting that:

We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a

¹²⁷ Engler, M. “The Trouble with CAFTA”, *The Nation*, January 16, 2004. @: <http://www.thenation.com/doc.mhtml?i=20040202&s=engler>

¹²⁸ CAFTA, Art. 15.9, para. 4.

¹²⁹ See for example: <http://www.encuentropopular.org/areas/tlc/artic013.htm>

¹³⁰ López, G. “Peligra cobertura universal de medicamentos”, *La Prensa Libre Online*, February 10, 2004. @: <http://www.prensalibre.co.cr/2004/febrero/10/nacionales07.php>

¹³¹ Bermudez Mora, op cit.

¹³² Avalós, “País defiende acceso a medicinas genéricas”, op cit.

*manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.*¹³³

The Declaration went as far as to specify a number of flexibilities to be included within the TRIPS agreement with regards to least developed countries and public health issues. These flexibilities include:

- a) The provisions of the TRIPS agreement will only be interpreted in light of the objectives and principles of the Agreement.
- b) The member states will have the right to enact legislation that allows for the granting of compulsory licensing, and to regulate legislation in whatever form they see fit.
- c) The member states will have the right to determine what they consider a national emergency, taking into consideration that public health concerns can be considered such.
- d) Each member state will be able to determine particular situations for the exhaustion of intellectual property rights within their territory.¹³⁴

It is evident that these provisions validated most of the policies designed to guarantee the widest possible access to medicines described in the earlier sections with two poignant exceptions, the issues of generic drugs and of parallel imports.¹³⁵ Paragraph 6 of the Declaration states that “*We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.*” The Council of TRIPS was given the responsibility of drafting and implementing a workable set of rules to fix this problem and report back to the WTO General Council before the end of 2002. Despite all of the positive indications set by the Declaration, representatives from developed countries successfully blocked the efforts to achieve an agreement within the Council of TRIPS, which had the approval of 144 countries.¹³⁶

Recent developments have been reached thanks to the mounting international public pressure to resolve this impasse – fuelled by almost universal condemnation of the aggressive tactics used by the United States during the post-Doha process. A new agreement reached by the WTO on export of generic drugs was published in August 2003, just before the Cancun Ministerial Meeting.¹³⁷ This agreement finally managed to implement the Paragraph 6 in the Declaration to attempt to provide some ways in which developing countries without producing capabilities would be able to obtain cheap or generic medicines.

Article 31(f) of TRIPS imposes restrictions on the export of products produced by compulsory licensing outside the territory in which it is granted. This has generally been considered as a prohibition on the export of generic drugs that are produced within a local market, not allowing a developing country to import generics when they cannot produce

¹³³ WTO. *Doha WTO Ministerial Conference: Declaration on the TRIPS agreement and public health*. Fourth WTO Ministerial Conference, Doha, Qatar. 9-14 November, 2001. @: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

¹³⁴ Ibid.

¹³⁵ Vandoren, P. “Médicaments sans Frontières? Clarification of the Relationship between TRIPS and Public Health resulting from the WTO Doha Ministerial Declaration”, *Journal of World Intellectual Property*, Vol.5 No. 1, January 2002, p.10-11.

¹³⁶ “US blocks cheap drugs agreement”, *BBC News Online*, December 21, 2002. @: <http://news.bbc.co.uk/2/hi/health/2596751.stm>

¹³⁷ WTO. *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health*. WT/L/540, August 30, 2003. @: http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

them.¹³⁸ The new WTO agreement implemented the recommendation in the Doha Declaration to allow for a temporary waiver for LDCs, allowing them to export generics under certain conditions. Another important provision is to continue to encourage the development of local pharmaceutical industries by means of technology transfer. The Paragraph 6 agreement states that “*Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector...*”

The system will operate in a two-pronged approach. Firstly, countries that are recognised as LDCs by the WTO will be able to use the paragraph 6 import system at any time and without needing to notify the TRIPS Council. Secondly, other developing countries may express their wish to import medicines to the TRIPS Council at any time, and they need to specify if they will use the system in whole or in a limited way.¹³⁹ It should be understood that if this agreement provides developing countries with the opportunity to import generic medicines that have been the subject of compulsory licences in other countries, it will also mean that this will be a tacit permission to manufacturing countries to export those medicines to the countries that have obtained this permission.

These developments arising from the Declaration must be taken as an excellent sign that there appears to be a renewed understanding of the importance of medicines in the international trade environment. Nevertheless, the new rules have been met with considerable scepticism from NGOs. MSF for example, has complained that “*The United States and other Developed Economies now have greater opportunities to pressure and stop developing countries from issuing compulsory licenses.*”¹⁴⁰

It is too early to ascertain if these fears are warranted, but the signing of this agreement must be welcomed as one of the most important steps towards providing access to imported generics by least developed nations that cannot manufacture them, and it may open the door for more positive steps.

4.2 The way forward

It has become difficult to attempt to chart the trends in the access to medicines debate. There have been a number of considerable victories for developing countries already mentioned, particularly the Doha Health Declaration, the Paragraph 6 Cancun health commitments and the two defeats suffered by the pharmaceutical companies in Brazil and South Africa. It must also be pointed out that generally, the TRIPS agreement already includes some important provisions with respect to access to medicines that allow for some important flexibility awarded to developing nations. There also appears to be a growing understanding in the international arena that recognises that there should be a balance between health and intellectual property rights, and that health should always be given better treatment when balancing the many interests involved.

On the other hand, there are some worrying trends taking shape. The Bush administration in the United States seems adamant in pursuing the signing and implementation of TRIPS-plus agreements, which considerably erode some of the existing and earned

¹³⁸ Correa, C. *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, World Health Organization, 2002. @: <<http://www.eldis.org/static/DOC11514.htm>>

¹³⁹ Matthews, D. “WTO Decision On Implementation Of Paragraph 6 Of The Doha Declaration On The Trips Agreement And Public Health: A Solution To The Access To Essential Medicines Problem?” *Journal of International Economic Law*, Vol.7, No. 1, 2004, pp.73-107.

¹⁴⁰ MSF. *Joint NGO statement on TRIPS and public health WTO deal on medicines: a “gift” bound in red tape*, September 10, 2003. @: <<http://www.accessmed-msf.org/prod/publications.asp?scentid=1292003916443&contenttype=PARA&>>

flexibilities allowed to developing countries in the area of generic medicines. Another strategy is to continue using punitive trade policies to make developing countries comply with the interests of the pharmaceutical companies. The threat of Special 301 list is a powerful bargaining tool for changing the behaviour of developing countries. It would seem evident that the lure of a share in big markets, and the problems posed by the export of generic medicines will enhance the possibility of having more legal battles between the multinational drug companies and developing countries like India. The United States in particular seems very interested in continuing to push for more restrictive international patent system. It is their claim that pricing does not affect access and that by providing better patent protection the developing countries will benefit from increased international investment and better trading conditions.¹⁴¹ But these arguments are not based in empirical data; in fact, little is understood about the relationship between pricing, investment and research. As stated by Abbott:

*Regardless of whether enhanced patent protection for pharmaceutical products may at some point in the future provide benefits to developing countries, there is no sound empirical basis for the United States to demand immediate introduction of such protection by developing countries, or to stand in the way of extending transition timetables for least-developed countries.*¹⁴²

Regardless of these considerations, there is still a vested interest in continuing to ensure patent protection in developed countries. There cannot be any doubt that despite all of the problems that have been mentioned already about the amount of research investment by the pharmaceutical companies, they are still spending a considerable amount of money in that field. It would be dishonest to ask the members of an industry to relinquish all of their intellectual property rights in order to provide access to medicines worldwide, but a balance must be struck between excessively restrictive monopolies and exceptional issues of public health.

The solutions to this problem then will not be simple. It is useless to propose the abolition of all pharmaceutical patents, or the immediate destruction of the TRIPS agreement. The solutions lies in the coming together of several areas, such as international trade, intellectual property rights, international assistance, government policy, and private assistance.

The pharmaceutical industry must understand first that it is in their best interest to provide some free or low-cost medicines to the poorest areas of the world. Many private initiatives are already underway to provide low-cost medicines to developing nations, such as PhRMA's Global Partnerships programmes, which give approximately \$580 million USD each year in assistance and medicines to developing countries.¹⁴³ These initiatives are on the increase, prompted by growing public pressure and investors clamouring for more ethical corporate policies.¹⁴⁴ Developed nations are also providing direct assistance to developing countries, with the United States donating \$2 billion USD globally in 2003 to the pharmaceutical industry.¹⁴⁵ The Bush administration has taken a significant interest to HIV in Africa, donating \$200 million USD in 2001, and \$500

¹⁴¹ Abbott, F. M. "The TRIPS Agreement, Access to Medicines, and the WTO Doha Ministerial Conference", *Journal of World Intellectual Property*, Vol.5 No. 1, January 2002, p.21.

¹⁴² Ibid; p.50-51.

¹⁴³ To learn more about the Global Partnerships programme, see: <<http://world.phrma.org/partnerships.html>>

¹⁴⁴ Boseley, S. "Investors pressure drug firms on pricing", *The Guardian*, March 25, 2003. @: <<http://www.guardian.co.uk/aids/story/0,7369,921361,00.html>>

million USD in 2003 and 2003 to this problem alone.¹⁴⁶ This investment has prompted the creation of the Global Fund to Fight AIDS, Tuberculosis and Malaria,¹⁴⁷ which consists of official government donations from developed nations, such as the funds from the United States, and considerable contributions from France and the UK. Another worthwhile effort is a joint project from the Clinton Foundation, the World Bank, UNICEF and the Global Fund to provide generic HIV medicines to developing nations.¹⁴⁸ The Clinton Foundation has also achieved some price reduction agreements of anti-retroviral drugs with some major pharmaceutical companies.¹⁴⁹

Donations and direct assistance are needed, but there should also be a strong recognition that any solution must involve trade. There are already concerns about the problem of the misdirection of medicines sent to developing countries, and then sent back to developed nations to profit from the immense price discrepancy. It is easy to see how generics exported to a poor country could make their way to a rich one. It is also easy to see how donated medicines could be misdirected for profit. To avoid some of the corrupt misdirection, the European Commission has adopted a set of regulations that attempt to stop the misdirection of drugs produced within the European Union from LDCs.¹⁵⁰ This regulation establishes a “tiered priced product”, which are medicines manufactured in the EU that are sold in developing countries at a 25% of what they cost in OECD countries, and with only a 15% profit margin.¹⁵¹ These medicines must also have a mark (see Figure 1). There is already a plan to implement similar provisions into the WTO’s health system.¹⁵² These provisions could create a better environment in which pharmaceutical companies and developed governments will be more willing to donate and export essential drugs to the neediest parts of the world.

Figure 1



However, the long term goal must be the need to get developing countries to be able to produce, manufacture and research their own pharmaceuticals. Donations and assistance only serve to alleviate the problem, but as the cases studied above demonstrate that real improvements in health figures can only be achieved through the creation of a local pharmaceutical industry. This means that the problem of pharmaceuticals is a problem of

¹⁴⁵ PhRMA. *Global Partnerships: Humanitarian Programs of the Pharmaceutical Industry in Developing Nations*. April 2003. @: <http://world.phrma.org/global_partnership.2003.pdf>

¹⁴⁶ Nakashima, E. “U.S. Urged to Increase Payments to AIDS Fund”, *Washington Post*, July 12, 2004, p.A10.

¹⁴⁷ More about the Fund here: <<http://www.globalfundatm.org>>

¹⁴⁸ See press release here: <http://www.theglobalfund.org/en/media_center/press/pr_040406.asp>

¹⁴⁹ See their press release here: <<http://www.cptech.org/ip/health/aids/clintonfoundation01152004.html>>

¹⁵⁰ Council Regulation (EC) No. 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines, OJ L 135/5, 3 June 2003.

¹⁵¹ Council Regulation (EC) No. 953/2003, Art. 3.

¹⁵² Matthews, op cit.

technology transfer; the issue will be once more the innovation and imitation dichotomy. Developing countries have to imitate technology that already exists in developed ones, and after a while there will be enough technological know-how to generate their own technology. This can already be seen in developing countries that have imitated health technology, such as the case in India.¹⁵³

All efforts then must go towards enhancing local production and research capabilities. Private efforts from the pharmaceutical companies in this respect should be welcome. Pharmaceutical companies should understand that capacity building and technology transfer can only work in their favour as a future strategy. If developing countries improve their health production standards, they will then become paying customers when they can afford medicines at better prices. As far as things stand, pharmaceutical companies are not profiting from poor countries, and there is no apparent immediate economic damage to them in promoting the transfer of health technology to the poorest regions of the globe. If things continue as they are, poor countries will remain under-developed, so the future revenue in sales from those countries will remain low. On the other hand, if these countries were to become developed, a potential market would be opened for these companies.

There should also be more efforts from the governments of developing nations, such as the case of Thailand, where the government has put considerable investment in making sure that the local generic industry can now produce high-quality drugs to combat the HIV epidemic. In fact, "*When the Thai Government Pharmaceutical Organization started producing the three-drug pill in March 2002, monthly treatment for one person plummeted to \$30 from \$500-\$750.*"¹⁵⁴ However, not all governments have the capability to fund efforts similar to those of the Thai government, not to mention the local capabilities to embark on such an undertaking.

But these solutions are only the start. Other solutions should be sought to encourage the transfer of technology in the health area. These solutions should be in par to those already described in this work, but there are other methods that can be used to enhance local production of medicines.

Conclusion

The price of drugs, patents and the state of international trade law in the shape of the regulation of intellectual property rights are just a part of the bigger picture when dealing with the problem of access to medicines.

As it was mentioned in the last section of the article, there are some serious efforts underway in order to provide developing countries with beneficial access to medicines, and these efforts have to be applauded and continued. The good will of developed nations in this respect cannot be denied.

But perhaps the debate will be brought forward by some recent happenings. The nightly news bulletins in developed countries are filled with stories about avian flu and the prospect of a pandemic that will kill millions of people. But it has also brought one issue back to the table, the access to medicines debate. There are reports that there is only one antiviral drug that deals with the current strain of the disease, a drug by Swiss company Roche called Tamiflu. There is growing concern that Roche is the only company with a

¹⁵³ Datt, N. *India recognized as global pharma outsourcing hub: Ernst & Young Global Pharma Report 2004*, Ernst & Young Press Release, July 2, 2004. @: [http://www.ey.com/global/download.nsf/India/ProgressionsPharma2004/\\$file/ProgressionsPharma2004.pdf](http://www.ey.com/global/download.nsf/India/ProgressionsPharma2004/$file/ProgressionsPharma2004.pdf) >

¹⁵⁴ "Generic drugs help HIV patients live longer", *MSNBC*, July 12, 2004. @: <http://msnbc.msn.com/id/5422798/>>

patent to produce this drug, and it is finally dawning on some people that this may not be such a good idea after all. This could highlight that while patents are generally beneficial, they can also prove dangerous in the time of an emergency.

As things stand, the status quo is not affecting the pharmaceutical companies. Profits are still flowing like never before, and potential advancements in biotechnology could translate into more sales in the developed countries. Nevertheless, there cannot be any doubt that the pharmaceutical companies can only benefit from the attempts by the developing countries to improve their living standards, as they will later become paying customers when they can afford the drugs. And one of the ways in which the less developed nations can improve those living standards is through access to basic medicines. As far as things stand, pharmaceutical companies are not receiving any sales revenue from poor countries, and there is no apparent immediate economic damage to them in allowing access to generic drugs by populations in need. If things continue as they are, poor countries will remain under-developed, so the future revenue in sales from those countries will remain low. On the other hand, if these countries were to become developed, a potential market would be opened for these companies.

With this in mind, there may be more willingness from the part of the developed world to address this issue.