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Graduate School of Development Studies

**Challenging the Obstacles Facing the Access to AIDS
Medicines: The Pharmaceutical Industry, Corporate
Social Responsibility, and the Developing World**

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Members of the Examining Committee:

Wil Hout
Paschal Mihyo

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Enquires:

Postal Address:

Institute of Social Studies
P.O. Box 29776
2502 LT, The Hague
The Netherlands

Telephone : -31-70-4260460
Telefax: -31-70-4260799
e-mail: postmaster@iss.nl

Location:

Kortenaerkade 12
2518 AX, The Hague
The Netherlands

Challenging the Obstacles Facing the Access to AIDS Medicines: The Pharmaceutical Industry, Corporate Social Responsibility and the Developing World

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Abbreviations and Acronyms

AIDS	Acquired Immune Deficiency Syndrome
ARV	Antiretroviral
Big Pharma	The top pharmaceutical corporations: Merck, Glaxo-Smith Kline, Pfizer, and Bristol Meyers-Squibb
CSR	Corporate Social Responsibility
HAART	Highly Active Antiretroviral Therapy
HIV	Human Immunodeficiency Virus
IPR	Intellectual Property Rights
NGO	Nongovernmental organization
PhRMA	Pharmaceutical Research and Manufacturers of America
R&D	Research and Development
TRIPS	Trade-Related Aspects of International Property Rights
WHO	World Health Organization
WTO	World Trade Organization

Glossary¹

Compulsory license: The authorization given by a judicial or administrative authority to a third party for the use of a patented invention, without the consent of the patentee, on various grounds of general interest (absence of working, public health, anticompetitive practices, emergency, national defense).

Generic drug: A pharmaceutical product which is not protected by a patent in force, and which is commercialized under a non-proprietary name or a brand name.

¹ This glossary is taken from a South Centre publication: Correa, Carlos. Integrating Public Health Concerns into Patent Legislation in Developing Countries. Geneva: South Centre, 2000, *xiii-xv*.

- Intellectual property:** A category of public law that generally includes copyrights, patents, trademarks, geographical indications, industrial designs, utility models, plant breeder's rights, integrated circuits rights and trade secrets.
- Parallel import:** The importation, without the authorization of the owner of an intellectual property right, of a protected product marketed abroad by the patentee or by an authorized party.
- Patent:** A title granted to protect an invention, generally for a twenty-year period.

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Chapter One:

This first, opening chapter begins with the introduction and aim of the research paper. The aim is then followed by the proposition guiding the research paper that explains that the intellectual property rights regime is an obstacle to affordable AIDS drugs in developing countries and the pharmaceutical industry has a corporate social responsibility to make drugs more accessible and affordable to those who need it. Next, the methodology of the research paper will be explained. Finally, the scope and limitations and structure of this thesis will be discussed.

1.1 Introduction

“The microbe is nothing; the terrain, everything.”²

The AIDS pandemic and the access to patented lifesaving medicines for developing countries has become one of the most visible and controversial international issues confronting development studies. AIDS is no longer seen as just a deadly disease, but as one of the greatest scientific, political, and moral challenges of our era. Medical science alone will not overcome the effects of the AIDS pandemic, if the antiretroviral drugs (ARVs) used to treat AIDS are so expensive that the vast majority of the people who need them are from developing countries and lack the financial capacity to afford the high prices set by the pharmaceutical industry. For this reason, the challenge lying ahead is how to save millions of lives by expanding access to AIDS medicines to those who desperately need it, while simultaneously fighting the socio-economic forces that have advanced the spread of HIV/AIDS.³ Today the major obstacle against expanding access to AIDS medicines is intellectual property rights, which allows patented AIDS medicines to be protected for twenty years from the marketing of and competition from cheaper drugs. This has made patents, profits and the access to AIDS medicines closely interlinked. Just as millions of people continue to suffer from AIDS related illnesses due to the high costs of AIDS medicines, the pharmaceutical industry has become one of the most profitable and politically influential industries in the world. This has led the research-based pharmaceutical industry to be accused of “waging an undeclared drug war” against poor countries by numerous NGOs and AIDS activists. In return, these accusations have led the pharmaceutical industry to respond to the criticism through the

² Louis Pasteur, qtd in. Ellwood, Wayne. “We all have AIDS.” *New Internationalist* 346, June 2002, 10.

³ Irwin, Millen, and Fallows. *Global AIDS*. Cambridge: South End Press, 2003, 3.

implementation of corporate social responsibility programs, which may potentially move pharmaceuticals beyond acts of philanthropy into an era where corporate policies are no longer an obstacle to the public health needs of the developing world.

This paper will focus on the current politics behind the AIDS pandemic and the growing political and economic dominance of the pharmaceutical giants. It will examine the role that pharmaceuticals have taken in the debate over the access to AIDS medicines in developing countries and will question the responsibilities of the industry and explore to what extent corporate social responsibility may help solve the AIDS pandemic. Through a discussion of the economic, legal, political and moral difficulties in increasing the access to AIDS medicines for the poor in developing countries, it will argue that the pharmaceutical industry has a social responsibility of ensuring that its policies and practices support public health policies and the fight against AIDS in developing countries. This paper is by no means a comprehensive review of all the pharmaceutical industry's efforts to practice corporate social responsibility in regards to AIDS. Rather, it is an attempt to offer an analytical typology for understanding the issues involved and its inherent complexities, with hopes for developing solutions. Just as Allan Brandt once stated that "AIDS will be the standard by which we measure not only our medical and scientific skill but also our capacity for justice and compassion," this paper will highlight one of the greatest challenges facing our era.

1.2 The Aim of the Research Paper

This research paper is concerned with exploring the relationship between corporate social responsibility and the giant research-based pharmaceutical companies of developed countries. In particular, it aims to look at this relation in regards to the availability of affordable HIV/AIDS medicines for the poor in developing countries. The paper will look at the obstacles facing AIDS treatment by highlighting the implications of the pharmaceutical industry's lobbying and promotion for global intellectual property rights and its possible significance in the fight against AIDS. This will be done by exploring the contesting arguments put forth by the pharmaceutical industry and that of AIDS and health activists in regards to patent protected medicines. The research paper will analyze

the contention that the current intellectual property rights regime is an implacable threat to the ability to substantially eradicate the AIDS pandemic. The paper will take the issue further, by questioning to what extent do pharmaceutical corporations have a social responsibility in making medical treatment accessible and affordable to the poor that are infected with HIV/AIDS. This will be achieved by examining the current position the pharmaceutical companies have taken within the AIDS crisis, drug pricing, and patent protection within the global regime of intellectual property rights. Next, the paper will incorporate the industry's position into the framework of corporate social responsibility (CSR) by researching to see if the drug companies have mandates on CSR, whether the pharmaceutical promotion of global patent protection standards coincide with CSR standards, while also exploring the possibilities that exist within the implementation of corporate social responsibility for increasing access to AIDS drugs. Finally, this paper will aim to develop solutions towards removing the obstacles that patent protected medicines create for developing countries that struggle to obtain affordable lifesaving AIDS drugs.

1.3 Proposition and Questions Guiding the Paper

This research paper is prompted by a concern that international trade rules, determined by governments and pharmaceutical companies of developed countries, and regulated under the auspices of the World Trade Organization (WTO), will further diminish the access of necessary HIV/AIDS treatment to poor people in developing countries. Underlying this is the proposition that the global intellectual property rights regime, which allows for lifesaving AIDS medicines to be patented, poses as a key barrier to sustainable, guaranteed access to vital medicines at affordable prices.

Another proposition guiding this paper is that intellectual property is not an inalienable right, such as the human right to life, dignity or even adequate health. Rather it is a right that was created for a purpose and that purpose is now being abused by powerful pharmaceutical companies. And this proposition carries the belief that business and more specifically, the pharmaceutical industry have moral and social responsibilities to society. This is because business is shaped by and depends upon societal values, such as honesty,

fidelity and diligence. These are the values that create a social infrastructure that allows business to occur, since without these values in place, widespread corruption and theft would make business impossible to conduct.⁴ These values are especially important in today's era of globalization that has led to the increased intensification and interdependence of economies and other spheres that markets influence. For this reason, the actions of the pharmaceutical industry must be held accountable, and if the pharmaceutical industry is actively pursuing company profit over the welfare of human society, changes must occur as both the developed and developing countries are not immune to the devastating consequences that the pandemic has on development and the global economy. Thus in the search for change and solutions, the following questions will guide this paper:

- What are the obstacles that hinder the access of AIDS medicines in the developing world and how has the pharmaceutical industry responded to these challenges?
- What are the arguments for and against intellectual property rights and what are the responsibilities of states and the private sector in correlation to these rights? Is a global norm for patent protection really in the best interests of developing countries and should a company be able to patent a product of important societal implications?
- Who should pay the cost of fighting the AIDS pandemic? In particular, does the developed world and pharmaceutical industry have an obligation to help the developing world and if so, how can they help?
- Finally, how far should business be expected to go in defining and promoting global standards in areas like corporate social responsibility, ethics, and human rights? And to what extent can corporate social responsibility play a role in changing the pharmaceutical industry's response to intellectual property rights in hopes to help increase the availability of affordable AIDS medicines in developing countries?

⁴ Resnik, David. "Developing Drugs for the Developing World." Developing World Bioethics. 1:1 (2001), 17-18.

1.4 Methodology

The research methodology of this paper is an analytical typology of how corporate social responsibility within the pharmaceutical industry has been implemented and the implications it has on challenging the obstacles facing AIDS drug access in the developing world. The paper analyzes the different challenges such as patent rights and questions whether the TRIPS agreement reflects the practice of CSR. It also studies the possible extent of influence CSR can have on providing solutions to help increase the availability of affordable HIV/AIDS drugs for the poor in developing countries.

In order to do this, the analysis of the topic both conceptually and empirically is based on a review of information available about corporate social responsibility, the pharmaceutical industry, and HIV/AIDS. The information used is based on a variety of secondary sources, which includes books and publications by academics, researchers and activists, journal articles, newspaper articles, and reports and publications from various NGOs and international institutions.

1.5 Scope and Limitations of Study

Due to limited time and space, in combination with the extensive field of CSR and the issues surrounding the AIDS pandemic, this paper does acknowledge a number of limitations.

- While this paper is demarcated to studying the issue of access to AIDS medicines, it's essential to acknowledge that there are many other obstacles that must also be tackled in order to make a significant impact on HIV/AIDS. The most difficult obstacle to overcome is the widespread poverty that plagues many developing countries, in which large sectors of the populations lack basic needs, such as the access to food and clean water, let alone quality healthcare. At the same time, many developing countries lack well-trained healthcare workers and the medical infrastructure that would be necessary to administer and monitor AIDS medicines. Additionally, armed conflict, corruption, social dislocation, and lack of political

will in countries where defense budgets are given priority to their public health budgets only further contribute to the problem. Thus, any solution must take on a multifaceted approach that extends beyond the pharmaceutical industry to include governments, civil society, and all other stakeholders responsible for care and treatment.

- Another limit to this paper is how the processes of globalization have impacted global health. This topic requires a paper in itself, as today's global political economy of neoliberal economics and free trade has had an enormous effect on the spread and impact of the AIDS pandemic around the world.
- The NGO community and global AIDS activists have played an essential role in responding to the pandemic from the beginning of the spread of AIDS to the present. They have placed an enormous amount of pressure on the pharmaceutical industry to widen their sense of social responsibility and accountability that has moved the industry into the deeper waters of CSR. Their influence merits acknowledgement that this paper will not be able to grant due to space constraints.
- Finally, even with lower prices of AIDS medicines, it is essential to note that its likely there will continue to be a large percentage of the population who will still be unable to afford the treatment due to the dire poverty they live in.

1.6 Structure of the Paper

Chapter one provides a brief introduction to the aim and scope of this research paper. Chapter two will give the conceptual framework which seeks to define the concept and significance of corporate social responsibility in the private sector. Corporate social responsibility will then be explored in its relationship to the research-based pharmaceutical industry. The conceptual framework will then provide the analytical lens in which to explore the problem of the AIDS pandemic. Chapter three will then begin with a brief background to the AIDS pandemic and the obstacles facing the availability of affordable AIDS medicines. This will be done by providing an overview of the World Trade Organization's most comprehensive international agreement on intellectual property rights that is auspicated under Trade Related Aspects of International Property

Rights (TRIPS) and is considered to be one of the greatest obstacles facing affordable AIDS treatment. The TRIPS agreement will be further examined by looking at the contesting arguments for and against property rights and how patented medicine impacts drug pricing and the development of new drugs. Next, the recent changes in the legal interpretations of TRIPS will be addressed along with the post-TRIPS options for developing countries' public health policies to expand access to AIDS medicines.

In the fourth chapter, the arguments that have been directed towards the pharmaceutical industry as a reason why they should implement CSR will be reviewed. Next, the actual implementation of corporate social responsibility within the pharmaceutical industry and all of its problems will be assessed. This assessment will be the basis for subsequently examining the problem of access to AIDS treatment in regards to whether there has been an implementation of corporate social responsibility within the TRIPS framework and to what extent the implementation of CSR has had on increasing access to drugs at affordable prices for developing countries. On the basis of this assessment, the fifth chapter will make some conclusions and recommendations on the ways in which CSR can be effectively implemented in the pharmaceutical industry in order to find effective solutions that balance the interests of the public with that of the private sector.

Chapter Two: Conceptual Framework: Corporate Social Responsibility and the Pharmaceutical Industry

This chapter explores the relationship between the pharmaceutical industry and corporate social responsibility (CSR). Initially, the concept and significance of CSR will be discussed, along with the different levels of engagement in CSR. Next, the relationship between CSR and the pharmaceutical industry will be explored. This will highlight the different definitions, views and approaches to CSR that relates to the pharmaceutical industry. The chapter will then conclude with a brief overview of the pharmaceutical industry's approach to CSR within the framework of the HIV/AIDS pandemic.

2.1 The Concept of Corporate Social Responsibility

Growing pressure on multinational corporations to take responsibility for their operations and its impact on society has resulted in an increasing number of large corporations beginning to address the concept of Corporate Social Responsibility (CSR). While CSR is not a new concept and has been around since the late 1950's and early 1960's, the field of CSR has grown exponentially in the past decade as more corporations are engaging in serious efforts to define and integrate CSR into their business practices. This strengthened emergence of CSR is due to the increased intensification and interdependence among states and people that has developed out of the globalization of economies and other spheres that markets influence. While markets are opening up to global competition through trade agreements and new information technologies; production, research, and marketing systems are developing increased competition, especially in the area of price competition.⁵ This has forced companies to be driven by the need to minimize costs, grow through mergers, and create significant market shares.⁶ Through this process, multinational corporations have begun to dominate the global economy by gaining significant power, wealth, and influence. These corporations have also begun to find themselves impacting more than the development of the economies in which they operate, as they find themselves enmeshed (directly or vicariously through their business partners) in controversial international social and environmental problems that are increasingly publicized in today's information technologies.⁷ As a result, there has been a movement towards promoting greater corporate accountability.

⁵ Reich, RB. The Future of Success New York: Knopf, 2001.

⁶ Beole, Fabig, and David Wheeler. "Shell, Nigeria and the Ogoni." Sustainable Development 9 (2001), 122.

⁷ Korten, D. When Corporations Rule the World San Francisco: Berrett-Koehler Publishers, Inc. 2001.

Simultaneously, businesses are beginning to acknowledge that they have wider responsibilities to the communities within which they operate. This has influenced civil society and corporations to begin developing codes of ethics and programmes for their re-enforcement, in order to meet the need for greater accountability and transparency to all stakeholders.⁸ And while the private sector's commitment to CSR has increased, there has also been increased rhetoric which has led to the development of diverse theories regarding how corporate responsibility is defined and what the term really implies.

There have been two approaches to CSR that have gained the most attention by its proponents; the merging of business and ethics viewpoint and the three dimensional viewpoint. The former approach has been studied by Ferrell and Fraedrich, who define corporate social responsibility as a concept that combines business and ethics. While they define business ethics as "the moral principles and standards that guide behavior in the world of business," they describe corporate social responsibility as "an organization's obligation to maximize its positive impact, and minimize its negative impact, on society."⁹ Together, these concepts create a multidimensional construct comprising of four entities of responsibility: economic, legal, ethical and voluntary philanthropic. The first level of responsibility is economic, since the purpose of a business is to produce services and goods that society needs and wants in a manner that perpetuates the business and satisfies its obligations to its investors. The next entity covers the legal responsibilities of business, which is to simply obey national and international laws and regulations. The third responsibility is ethical, which covers the activities or behaviors of a business that are expected by society, but have not yet been defined in the form of law. Lastly, the voluntary philanthropic responsibilities are the activities and behaviors desired by society that help contribute to the general public in terms of quality of life and society's welfare.¹⁰ Together the actual significance of these four entities of responsibility has changed with the forces of globalization from a 'make and sell' approach to a 'serve and respond' approach, which forces businesses to engage in a much

⁸ Beole, Fabig, and David Wheeler. "Shell, Nigeria and the Ogoni." *Sustainable Development* 9 (2001), 123

⁹ Ferrell, O.C. and J. Fraedrich. *Business Ethics* Boston: Houghton Mifflin, 1997, 6 and 67.

¹⁰ Dimitriadis, Zoe. "Business Ethics and Corporate Social Responsibility in the e-Economy: A Commentary." *Electronic Journal of Business Ethics and Organization Studies* 8:1 (2003), 2-3.

wider level of operations and relations within communities, while also being adaptable and accountable to the unpredictable requests and risks that may emerge from society.¹¹

The second definition and approach to CSR that has gained a large consensus among multinational corporations is the tridimensional approach. The World Business Council on Sustainable Development defines 'corporate responsibility' in three dimensions: the financial, the social and the environmental.¹² Similarly, Andriof and McIntosh use these three dimensions as areas in which a company is responsible.¹³ This is also closely related to Elkington's 'triple bottom line' theory of sustainable development that advocates for firms to achieve balanced progress on economic prosperity, social justice (or equity), and environmental quality.¹⁴ These theories consider the three CSR dimensions to make an overlapping tridimensional impact on society, which then places the heart of the CSR debate around the impact a company can make on poverty, lack of equal opportunities, the environment, consumer concerns, and employee welfare.¹⁵ And for this reason, research shows that the top five priorities of problems that corporations are dealing with today are: poverty, environmental protection, human rights, education, and drug and alcohol abuse. US corporations generally rank education and drug and alcohol abuse as top priorities, while European and Asian executives focus on human rights, poverty and environmental protection.¹⁶

While the CSR definitions mentioned above reflect the belief that business has a responsibility to act in an ethically and socially responsible manner, there are many opponents to CSR that question for what and whom are companies responsible for when pursuing business. Some believe that the only responsibility of a company is to ensure

¹¹ Dimitriadis, Zoe. "Business Ethics and Corporate Social Responsibility in the e-Economy: A Commentary." *Electronic Journal of Business Ethics and Organization Studies* 8:1 (2003), 5.

¹² Watts, P. and R. Holme. *Meeting Changing Expectations: Corporate Social Responsibility*. Geneva: WBCSD, 1999.

¹³ Andriof and McIntosh. *Perspectives on Corporate Citizenship* Sheffield: Greenleaf Publishing Limited, 2001.

¹⁴ Elkington, John. *Cannibals with Forks*. Gabriola Island, BC: New Society Publishers. 1998.

¹⁵ Deresky, H. *International Management* (4th ed.) Upper Saddle River: Prentice Hall, 2003.

¹⁶ Harila, H. and K. Petrini. *Incorporating Corporate Social Responsibility* Lulea: Lulea University of Technology, 2003, 4.

maximum profit to its shareholders, who should in turn decide how to use the resources.¹⁷ This is in line with Milton Friedman's statement that "the business of business is business" and the sole social responsibility of a company is to maximize profits for its shareholders.¹⁸ Despite these views, many proponents and opponents of CSR agree that business operations should extend beyond the single prospect of making money and that the demeanor of a business affects both the inside and outside of the company.¹⁹ And while this view has become quite commonplace, the degree that a business chooses to extend beyond the realm of profit maximization and through CSR engagement differs from company to company.

Jean-Francois Rischard uses a five stage classification of business engagement that a business can have within corporate social responsibility, which moves from a low to high level of responsibility and implementation. The first stage of engagement is through charity, where the company's key motivation is philanthropic. The next stage occurs when a business implements a defensive CSR model, where its key motivation is to protect the reputation of the company. The third stage is the offensive CSR, where the aim is to be recognized as a world-class company that engages in socially responsible behavior. The fourth stage occurs when the business becomes an agent of development, with the motivation to help out where governments have failed. The last stage of engagement is when the business becomes a global problem solver, where they join others in order to respond to urgent global problem solving.²⁰ Today, many of the world's leading companies are adopting all five of these approaches in order to engage in wider societal and development challenges. And while many companies continue to operate in the first three stages, the last two stages have the greatest potential to make a positive impact on development.

¹⁷ Andriof and McIntosh. Perspectives on Corporate Citizenship Sheffield: Greenleaf Publishing Limited, 2001.

¹⁸ qtd in. *ibid*, 13.

¹⁹ *ibid*.

²⁰ qtd. in Davies, Robert and Jane Nelson. "The Buck Stops Where?" International Business Leaders Forum January 2003 <<http://www.pwbif.org/csr>> 15 August 2003, 5.

Once a company chooses to fully engage in CSR and take on the challenges of development, the company must adopt a number of measures of integrate CSR into their operations. A corporation's level of engagement must then be translated into concrete codes of conduct and practices, along with legally enforceable standards and monitoring and enforcement mechanisms. Just as each company integrates CSR into their organizational framework in different ways, the concept and methods to incorporate CSR are continuously evolving as different international organizations work to develop guidelines and benchmarks for the private sector that reflects transparency and commitment to CSR. In the end, there are no easy answers in defining the boundaries and actions of business. CSR becomes a matter of balance. A company must balance the interests of all the stakeholders involved, while also balancing all of its responsibilities. Thus, CSR provides a lens to analyze not only how far *should* a company go, but also how far *can* a company realistically go in helping society achieve economic prosperity, environmental protection and social equity.

2.2 Corporate Social Responsibility and the Pharmaceutical Industry

Corporate Social Responsibility (CSR) has developed as the pharmaceutical industry's response to increased public concern about the accountability and the social, environment and economic impact of multinational corporations. While CSR has mainly been linked to public relations and reputation risk management, it has also played an important role in mapping out what research-based pharmaceutical corporations can and should do in regards to the growing inequalities between developing and developed countries- inequalities that help create and perpetuate poverty. Thus, CSR forces companies to rethink their attitudes towards markets and profits, while working to improve the impact that their business has on people and development.²¹ This is because CSR goes beyond corporate philanthropy by exploring the role that corporations can and should play in addressing some of the deep inequalities between developed and developing countries. And this is an area where the pharmaceutical industry's response to CSR is beginning to explore to ensure that its policies and practices support the fight for health in the developing world. In order to ensure socially responsible corporate behavior, the

²¹ Oxfam, Save the Children and VSO. Beyond Philanthropy. Oxford: Oxfam, 2002,10.

pharmaceutical industry has had to question and explore how it defines and implements its social responsibilities within CSR.

So what are the social responsibilities that apply to the pharmaceutical industry and what is their significance? Resnik argues that the pharmaceutical industry has two kinds of social responsibilities. The first responsibility is beneficence, in which the pharmaceutical industry should work to do good and avoid doing harm, by finding the greatest balance of benefits/harms for society. The second responsibility is justice, which means the pharmaceutical industry should distribute the benefits and burdens equitably.²² The rationale behind the social responsibility of beneficence is fairly forthright and uncontroversial, since most countries have legal laws regulating the testing, manufacturing and marketing of drugs to ensure that safety and standards are upheld to the highest degree. However, the application of beneficence is a bit more complex as societies must assess the benefits and harms in the decision to approve a new drug, such as whether the benefit of the drug outweighs potentially harmful side effects. Thus, there needs to be a balance between the benefits and harms of a medicine.²³

The rationale behind the second social responsibility of justice is more complex and controversial, but is strengthened by the growing recognition by the pharmaceutical industry that companies should play a role in helping to promote access to medicines. For example, Brody argues that pharmaceutical prices should not be an obstacle in making important medicines accessible.²⁴ Another view argued offered by Spinello, is that pharmaceutical pricing should apply egalitarian principles in order to ensure that drug prices promote social justice.²⁵ At the same time, both of these authors acknowledge that there must be a balance between the duty of justice and that of the practical need to make a reasonable return on investment. Still others have argued that corporations must distribute the benefits and burdens of research and research

²² Resnik, David. "Developing Drugs for the Developing World." Developing World Bioethics 1:1 (May 2001), 18-19.

²³ *ibid*, 19.

²⁴ Brody, B. "Public Good and Fair Prices: Balancing Technological Innovation with Social Well Being." Hastings Center Report 26,2 (1996), 5-11.

²⁵ Spinello, R. "Ethics, Pricing, and the Pharmaceutical Industry." Journal of Business Ethics 11 (1992), 617-626.

participation equitably. This follows the belief that the members in society who participate in medical studies and research should be fully compensated for their participation in the form of benefits. In particular, the participants should receive the drugs at a reasonable price as it's not fair to place people at risk without reasonably assuming there will be benefits.²⁶ While the pharmaceutical industry does have a certain degree of obligation to be socially responsible, the obligation is not absolute nor can its moral responsibilities be easily measured. For this reason, there is no uniform approach to defining and integrating CSR into the policies and practices of the pharmaceutical industry. However, an increase of public pressure has helped move the pharmaceutical industry to systematically acknowledge that it has a more important role in ensuring that the vital medicines it produces benefit all people.

The most important role that the pharmaceutical industry emphasizes as its primary societal responsibility is the discovery and development of new drugs and vaccines. The industry currently has over 100 new drugs and vaccines in the development processes for HIV/AIDS.²⁷ The industry has also undertaken many additional activities to improve the access to medicines in developing countries, by activities such as participating in donation programs, investing in health related education and prevention programs, and establishing global safety and ethical standards into daily business practice.²⁸

In general, the pharmaceutical industry has embraced the idea of CSR and that it is a social entity, but it has been reluctant to fully implement CSR. For example, pharmaceutical giant Merck says in its statement of values: 'Our business is preserving and improving human life,' and goes on to claim, 'we are committed to the highest standards of ethics and integrity.'²⁹ However, the company's policy regarding the access to AIDS treatment has so far been largely defined in terms of philanthropic ventures. At

²⁶ Resnik, David. "Developing Drugs for the Developing World." *Developing World Bioethics* 1:1 (May 2001), 20.

²⁷ Bale, Harvey. "The Pharmaceutical Industry and Corporate Social Responsibility." 2003 <<http://www.responsiblepractice.com/english/insight/ifpma>>. 19 of August, 2003.

²⁸ *ibid.*

²⁹ Cohen and Illingworth. "The Dilemma of Intellectual Property Rights for Pharmaceuticals: The Tension between Ensuring Access of the Poor to Medicines and Committing to International Agreements." *Developing World Bioethics* 3:1 (2003), 44.

the same time, as a response to growing public pressure and the AIDS pandemic, the industry has responded by increasing its number of philanthropic programs (especially in the area of joint public private initiatives) during the past four years. Despite the increase in philanthropic programs, the pharmaceutical industry has not yet made a systematic and collective effort to address the issue of pricing, an area which they could have a significant impact.³⁰ For example, the response that has been taken by GlaxoSmithKline, the world's largest maker of AIDS drugs, has been a public commitment to make AIDS drugs more affordable through sustainable preferential pricing. This announcement has led to prices being reduced by as much as a third to qualified patients in 63 different countries.³¹ While these are first steps towards making treatments more affordable to the poor, the prices are still higher than many generic versions that smaller drug companies in India and Thailand are able to make. Yet, these generic versions are unavailable due to current patent protection laws.

The pharmaceutical industry has made and continues to expand its voluntary efforts in CSR, which has made it recognized as not only a leading CSR performer, but increasingly as a key player in the area of global health.³² The AIDS pandemic and the capacity of the poor to pay for patented medicines have become fundamental to global health and development. Not only has AIDS changed the face of humanity more than any other disease, it has become the pandemic that will challenge the pharmaceutical industry's intentions and ability to implement changes more than anything else.³³ This paper looks at the nexus of patents, inflated drug prices and the position of the pharmaceutical industry to begin analyzing to what extent CSR has contributed to finding solutions to the access to AIDS medicines in the developing world. Only by fully exploring 'the pathologies of power' of HIV/AIDS and its methods of treatment can we consider if the pharmaceutical industry has sacrificed equity for efficiency and profits.³⁴

³⁰ Oxfam, Save the Children and VSO. Beyond Philanthropy. Oxford: Oxfam, 2002, 10.

³¹ Abelson, Reed. "Glaxo Will Further Cut Prices of AIDS Drugs to Poor Nations." The New York Times April 28, 2003, 1.

³² Bale, Harvey. "The Pharmaceutical Industry and Corporate Social Responsibility." 2003 <<http://www.responsiblepractice.com/english/insight/ifpma>>. 19 of August, 2003.

³³ George, Susan. The Lugano Report London: Pluto Press, 1999, 140.

³⁴ Paul Farmer qtd. in Heywood. "Drug Access, Patents and Global Health." Third World Quarterly 23:2 (2002), 222.

This answer will provide insight into the relationship between CSR and the pharmaceutical industry, as to whether CSR has become a fully integrated element in the industry's strategies and operations and whether or not it can be used as a mechanism to promote effective healthcare solutions that will benefit all of society.

Chapter Three: The AIDS Pandemic and the Obstacles Facing Access to AIDS Medicines

This chapter provides a brief background to the AIDS pandemic and the challenges surrounding the availability of affordable AIDS drugs for developing countries. Next, it examines the TRIPS agreement within the Intellectual Property Rights Regime, the costs and benefits of patent protection, and the impact TRIPS has had on the availability of affordable AIDS drugs for developing countries. Next, it will explore the post-TRIPS options that developing countries may implement in their public health policies in order to increase access to HIV/AIDS medicines. Throughout this chapter, the position and actions of the pharmaceutical industry will be examined.

3.1 Background to the AIDS Problem and the Access to AIDS Medicines

HIV/AIDS is a global public health threat of staggering proportions. Since the disease was discovered twenty years ago, twenty-two million people have died from AIDS related illnesses with an additional thirty-six million people now infected. Perhaps more than any other disease, HIV/AIDS illustrates the entrenched and growing global inequality and exclusion that is simultaneously expanding the gap between the North and the South.³⁵ Today, the problem of HIV/AIDS is overwhelmingly a problem of the South, with over 95% of its victims living in developing countries with the most devastating impact occurring in sub-Saharan Africa where it has claimed more than two-thirds of its victims. With more than 15,000 people becoming infected and 8,000 dying daily, the economic and social effects that HIV/AIDS has on the processes of development are far outreaching and long-lasting.³⁶ Besides being responsible for a massive increase in the death rates of men and women in their most productive years, the advent of the AIDS epidemic has been detrimental to the growth of the labor force, has caused an enormous increase in the number of orphans, while also playing a terrible toll on households, education, health systems, and business sectors.³⁷ Just as good health boosts labour productivity, educational attainment, and income, poor health contributes to an increase in poverty, which is a recognized barrier to the economic growth and

³⁵ Thomas, Caroline. "Trade policy and the politics of access to drugs." *Third World Quarterly*. 23:2 (2002), 252.

³⁶ Irwin, Alexander. *Global AIDS* Cambridge; South End Press, 2003, 61.

³⁷ UNAIDS. *Report on the Global HIV/AIDS Epidemic* (June 2000) Geneva: UNAIDS, 2000.

development of developing countries.³⁸ In the end, HIV/AIDS inadvertently hurts the entire global economy from global prosperity and economic development.

However, during the last decade, new hopes of fighting the spread of AIDS have been discovered. While these hopes are not the solution to the problem, they help pave the foundation necessary for the global eradication of AIDS.³⁹ The hope emerges from the development of drugs that help to delay the growth and speed of HIV's attack on the immune system while also reducing the patient's likelihood of infecting others. Today there are three types of antiretroviral drugs (ARVs) approved by the U.S. Food and Drug Administration (FDA) for the treatment of HIV/AIDS; these are nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors and protease inhibitors. When these three types of drugs are used in combination creating a so-called "drug cocktail" (also known as highly active antiretroviral therapy or HAART), they have been able to dramatically increase life spans by 75%, while also substantially improving the life quality of AIDS patients. In the United States alone, the mortality rates from HIV/AIDS have dropped by 75% in just three years.⁴⁰

Yet despite the remarkable results of the ARV drugs, the exorbitant drug prices of this ideal method of treatment remains largely accessible only to those living with AIDS in developed countries. In the late 1990's, the annual costs of HAART therapy along with laboratory tests and provider fees could exceed \$20,000 per patient. In 2001, HAART costs ran for more than \$10,000 per patient per year. Today, the average cost of HAART treatment is significantly lower, primarily due to activist pressure on the pharmaceutical industry and price concessions from research-based drug manufactures.⁴¹ Yet, despite the lower pricing, the medicines continue to be unnecessarily high and out of reach for the developing world where the majority of the population lives on less than two dollars a day. For this reason, widespread AIDS treatment has been restricted to less than 5% of

³⁸ Lennox, Jean and Dag Ehrenpreis. "Good health A cornerstone of development." *OECD Observer* 237 (2003), 28-30.

³⁹ Rothenberg, Alexander. "AIDS in sub-Saharan Africa and the Failure of Medical Technology Transfer." www.theshortrun.com/studies/drugpatents.pdf, 6.

⁴⁰ Gillespie-White, Lee. "Patent Protections and Patients' Access to HIV/AIDS Drugs in sub-Saharan Africa." International Intellectual Property Institute's Fraser Forum, 2001, 2.

⁴¹ Irwin, Alexander. *Global Aids: Myths and Facts*. Cambridge: South End Press, 2003, 74.

those infected with HIV/AIDS in developing countries who are able to afford the high prices set by the pharmaceutical industry. The chart below demonstrates the large gap between those who are receiving HAART therapy and those who need it within developing countries and how coverage varies according to region due to a diversity of responses related to varied public health policies and drug pricing contracts developed between the pharmaceutical industry and specific countries that will be discussed in the following chapter:

**Coverage of Antiretroviral Therapy (ART) in developing countries, Dec. 2002
(adults by region)⁴²**

Region	Number of people on ART	Estimated Need	Coverage
Sub Saharan Africa	50,000	4,100,000	1%
Asia	43,000	1,000,000	4%
North Africa, Middle East	3,000	9,000	29%
Eastern Europe, Central Asia	7,000	80,000	9%
Latin America, Caribbean	196,000	370,000	53%

To date, access to AIDS medicines has been largely determined by socio-economic status and geography (although race and gender are also determinants), which is why AIDS/HIV has often been called a “global medical apartheid.” AIDS points to the fundamental global inequalities and patterns of injustice enmeshed into today’s international political economy, which divides the rich and the poor into a two-tiered system where the rich get drug treatment, while the poor must focus on prevention and avoid the expenses and technical challenges of treatment programs.⁴³ While the AIDS epidemic originally infected the wealthy and the poor the same, it has gravitated to the most marginal groups in society and now concentrates in the lowest social strata. AIDS will continue to affect those most vulnerable to infection and poverty; unless there is a shift of course in the international response to AIDS that works to fight the global

⁴²International HIV Treatment Access Coalition. “A Commitment to Action for Expanded Access to HIV/AIDS Treatment.” Geneva: World Health Organization, 2002, 1.

⁴³ Irwin, Alexander. *Global AIDS*. Cambridge, South End Press; 2003, 60 and 61.

apartheid by solving the obstacles that makes essential AIDS medicines inaccessible to the poor. One of the key actors involved is the research-based pharmaceutical industry whose pricing policies often make them adversaries rather than allies in the fight. Winne Madikizela-Mandela, once stated “The war against AIDS begins with the struggle against the drug companies.”⁴⁴ This is because the pharmaceutical industry has faced growing criticism for its policies and practices in the issue of access to medicines that appears to place profits over people. This chapter will explore the debate regarding AIDS medicines pricing by examining the pharmaceutical industry’s role in promoting patent protection and its relationship to monopoly pricing, while also looking at other factors that have had profound implications on the ability of developing countries to access affordable AIDS medicines.

3.2 The Intellectual Property Rights Regime:

One of the most significant developments to emerge out of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) is the signing of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which is administered under the World Trade Organization (WTO). TRIPS is one of the core agreements that is legally binding to all WTO members. The aim of the agreement is the strengthening and harmonizing of the protection of intellectual property rights (IPR) at the international level, by stipulating that all members embrace a set of universal minimum standards for IPR protection. The TRIPS agreement has been an unprecedented initiative of the industrialized world, because the initiators of TRIPS shaped the terms of the agreement to reflect the prevailing standards of developed countries, while forcing developing countries to substantially strengthen its legal protection of IPRs and synchronize its IPR standards with those of developed countries, in particular the USA.⁴⁵ At the same time, there was a great amount of corporate influence in the introduction and development of intellectual property rights to the WTO agenda as many companies lobbied heavily for the actualization of TRIPS. The pharmaceutical industry was one industry that played a

⁴⁴ qtd. in Borchardt, John. “More than Altruism behind donations of AIDS drugs to Africa.” *The Scientist* December 8 2000, <<http://www.biomedcentral.com/news/2001208/03>> September 4, 2003, 3.

⁴⁵ L.C. Lai, Edwin and Larry D Qui. “The North’s intellectual property rights standards for the South?” *Journal of International Economics*. 59 (2003), 184.

key role in the formulation of TRIPS, as representatives of the drug companies occupied important positions on the special US presidential trade advisory board created to develop policy. Even before TRIPS was signed, corporations had lobbied for the US Trade Representative (USTR) to demand stricter protection of US corporate interests abroad by using the threat of trade sanctions. In particular, they used the 1988 'Special 301' provision that granted the USTR the right to impose sanctions on states with weak patent laws.

Prior to the TRIPS agreement, the majority of developing countries had either no or only partial patent protection within the pharmaceutical sector. Historically, some of the countries had even restricted patentability of drugs on public policy grounds. India, for example, had excluded patents on medicines and food in order to prevent 'profiteering from life and death.'⁴⁶ Thus, the implementation of patent protection is a relatively recent phenomenon for many countries that carries a variety of costs and benefits; however before examining them, it's essential to understand the agreement.

The TRIPS framework covers seven parts and 73 articles which establish the minimum standards in the field of patent protection for 'new and inventive' products. The objectives of the TRIPS Agreement are set out in Article 7:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.⁴⁷

Through TRIPS, inventions are provided with a minimum of twenty years of exclusive patent protection and marketing rights within and between the WTO's 146 member countries. The TRIPS agreement also fully integrates corporations that create innovations in all fields of technology, including pharmaceuticals and biotechnology products and processes. Prior to TRIPS, approximately 50 developing countries and several developed countries had either excluded medicines from being patented, or gave

⁴⁶ Shiva, Vandana. Protect or Plunder? London: Zed Books, 2002, 88.

⁴⁷ qtd. in Watal, Jayashree. Intellectual Property Rights in the WTO and Developing Countries. The Hague: Kluwer Law International, 2001, 451.

patents only for production processes rather than the product itself.⁴⁸ For this reason the TRIPS agreement gave developing countries until 2000 and Least Developed Countries (LDCs) until 2006, to bring their national legislation up to WTO standards. Of the developing countries that did not previously patent products, they were granted until 2005 to fully implement TRIPS. However, all countries must currently offer 'market exclusivity,' which is the equivalent of patent protection to drugs filed for patents after 1995. Thus, the widespread effects of the TRIPS agreement have already begun to be seen in many developing countries. For nations such as India, Argentina, and Brazil, which prior to 1995 granted no product patents and hosted prosperous generic drug industries, the ability to supply generic versions of drugs will be restrained. And for the 30 of the 49 LDCs that have already become WTO members, along with the additional ten that are in the process of accession to the WTO, who once relied on other countries for generic drugs, their ability to import necessary medicines may be limited.⁴⁹ For this reason, TRIPS has left many developing countries forced to navigate through the ambiguities and loose definitions of the legal text in order to pursue alternative means of increasing access to medicines and incorporate more flexible interpretations of TRIPS into their national legislations.

From a public health policy perspective, governments have two important policy instruments that can help them balance the claims of the patent holders with the interests of the general public. The first of these alternative means is compulsory licensing, which is when a patent is overridden for payment of a royalty. The second alternative is differential pricing, which allows developing countries to purchase the patented drug for considerably less than the product cost in developed countries.⁵⁰ TRIPS provides a very basic framework about when and how this can be done, with very little written about the procedures of prerequisites for invoking the exceptions. Thus, these articles and measures have become an area of dispute as developing countries are using the articles

⁴⁸ Oxfam. Patent Injustice. Great Britain: Oxfam, 2001, 23.

⁴⁹ Scherer, F.M and Jayashree Watal. "Post-TRIPS Options for Access to Patented Medicines in Developing Nations." Journal of International Economic Law (2002), 914.

⁵⁰ Panos Institute. Patents, Pills and Public Health. London: The Panos Institute, 2002, 2.

loopholes in order to use compulsory licensing as a post TRIPS option for creating access to patented medicines.

3.2.1 Main Provisions in TRIPS that Relate to Public Health Policies

There are three provisions with the TRIPS agreement that deals with patent issues from the perspective of public health. These provisions focus on issues relating to the access of medicines through the promotion of increasing the affordability of medicines. By interpreting and applying these provisions through a public health perspective, developing countries can provide safeguards for their public health interests. Through the flexibility of interpretation, it allows governments to make exceptions to patent holders' rights in the case of national emergencies and anti-competitive practices. However, the degree of flexibility of these provisions and the actual ability of developing countries to use these safeguards has been subject to ongoing discussion and at times the threat of trade retaliation. The significance of the TRIPS provisions most appropriate to public health are as follows:

- Article 27.2: Allows states to restrict the patentability of inventions, if they pose a threat to human life or health (but this does not allow blanket restriction).
- Article 30: States the limit of exclusive privilege granted on patents, however a state can not reject the patentability of a given drug or invention, but only regulate its use. Included are exceptions such as: 'limited exceptions' to monopoly rights; exceptions should not 'unreasonably conflict' with the exploitation of patent; exceptions should not unreasonably prejudice the legitimate interests of the patent owner.
- Article 31: This is the regulatory framework for compulsory licensing, which is permissible under TRIPS, but under very strict conditions: case by case basis with authorization on commercial terms unless in situation of national emergency. The positive aspect of this is that there are no limitations on the purposes for which compulsory

licenses can be granted and allows states to determine what constitutes a national health emergency.

While many governments and pharmaceutical companies believe that the necessary flexibilities are already found in TRIPS, others question whether they are sufficient and believe that TRIPS, in its current wording, is a barrier for developing countries' obligations to promote the health of their people. The UN Development Programme (UNDP) has said that "Current practices are preventing the fair implementation of TRIPS...A single set of minimum rules may seem to create a level playing field, since one set of rules applies to all. But as currently practiced, the game is not fair because the players are of such unequal stress, economically and institutionally."⁵¹ It is for this reason, that many public health activists believe that there is a strong case to be made, legally and morally, for the TRIPS agreement to be properly amended and/or repealed in order to help support the access to affordable patented medicines.⁵²

3.3 Cost and Benefits of Intellectual Patent Protection

This section deals with the implications of the TRIPS Agreement in different areas of crucial importance for solving public health issues which coincides with the ability of developing countries to increase their access to patented drugs. Just as many African and South American governments, public health activists and scholars have denounced TRIPS for sacrificing the health of developing countries in order to protect pharmaceutical firms' revenues, the pharmaceutical industry has responded that its patent-protected monopoly pricing is necessary to promote research on breakthrough drugs of value to all, including the poor. Rather, the industry promotes increasing access of drugs to the world's poor through the means of foreign aid from wealthy nations, donations from pharmaceutical firms and "protection for international price discrimination against the threat of 'grey market' arbitrage."⁵³ Consideration of these

⁵¹ Panos Institute. Patents, Pills and Public Health London: The Panos Institute, 2002, 22.

⁵² Canadian HIV/AIDS Legal Network. TRIPS and Rights Toronto: Canadian HIV/AIDS Legal Network, November 2001, ii.

⁵³ Bloche, Greg. "WTO Deference to National Health Policy: Toward an Interpretive Principle.: Journal of International Economic Law, (2002) 838.

competing claims from the pharmaceutical industry and its critics on the costs and benefits of the TRIPS agreement will be addressed next.

3.3.1 Innovation

There are competing claims of the economic and social impact that the full or partial implementation TRIPS will have on developing countries. The argument most often most voiced in favor of patent protection is that patents are essential for the development and research of new drugs. Thus, patents reward people for their inventions, which helps to encourage and stimulate further technological innovation. This is because patents work on the notion that people are not inherently altruistic and expect rewards for their endeavors, especially when the endeavors require great investment and have a high rate of failure.⁵⁴ For this reason, the profits gained from patent protection is considered fundamental to the Research and Development (R&D) expenses required to develop, produce and test new pharmaceutical drugs, which range from a contested \$250 to over \$800 million per drug.⁵⁵ Another argument in favor of patents is that they may help stimulate the economic development of a country, since patents may help encourage greater technology transfer between countries, increased foreign direct investment, while giving domestic enterprises the ability to achieve economies of scale in national markets.⁵⁶ While this argument will be considered more in the following section, the outcome of all of this could then be increased economic development, which would help eradicate poverty in developing countries. It has also been argued that patents disseminate information that may have been previously kept secret, since one of the prerequisites of patent protection is disclosing all information about the production process and contents of the product, which may in turn help advance other R&D initiatives.⁵⁷

⁵⁴ Joseph, Sarah. "Pharmaceutical Corporations and Access to Drugs." Human Rights Quarterly 25 (2003), 431.

⁵⁵ Irwin, Alexander, Joyce Millen and Dorothy Fallows. Global AIDS: Myths and Facts. Cambridge; South End Press. 2003, 117.

⁵⁶ Maskus, Keith. Intellectual Property Rights in the Global Economy." Washington DC; Institute for International Economics, 2000, 11.

⁵⁷ Joseph, Sarah. "Pharmaceutical Corporations and Access to Drugs." Human Rights Quarterly 25 (2003), 431.

Despite the positive factors that could come out of patent protection, many critics have argued against the desirability of patent protection in developing countries. The critics' main argument is that the burden falls heaviest on the countries least able to bear it and that most of the positive factors of patent protection are myths. Stronger intellectual property rights may invite the cartelization of the drug industry through monopoly pricing, which eliminates competition and keeps drug prices high. The pharmaceutical industry justifies inflated drug prices over the marginal price of production with patents in order to help absorb the costs involved in developing the drug.

Thus, the argument against TRIPS stresses that the inflated drug prices restrict the ability of the poor to access necessary medical treatment in developing countries where poverty abounds and offers little subsidized health care. Another concern raised is about what kind of innovation is being funded by R&D budgets in the pharmaceutical industry. Just as the pharmaceutical industry justifies the necessity of high drug prices in order to fund the development of new drugs, it is uncertain whether the high medicines prices are justified since there has been little evidence or developments made that suggest the pharmaceutical companies use profits to help promote the development of drugs related to the needs of the poor. This problem of innovation deficit is further explored in Chapter Four.

3.3.2 Foreign Direct Investment

TRIPS has often been thought of as a tool to increase the flow of foreign direct investment within developing countries, as the existence of intellectual property rights standards can be a deciding factor that may encourage potential foreign investors to locate their production facilities in a country with intellectual property rights protection. However, the harmonization of IPRs under the TRIPS Agreement means that the extent to which IPRs are protected in a country is likely to become a less significant issue in investment decisions. In addition, the protection of IPRs may actually reduce the flow of foreign direct investment since TRIPS does not provide incentives for a corporation to engage in foreign direct investment for the purpose of manufacturing products in or close to attractive foreign markets. This can be seen in the case of patents, since there is no

obligation to work the protected technology locally, thus, a company may choose to locate production in the home country and export the patented products, rather than manufacture the protected innovations abroad.⁵⁸

3.3.3 Transfer of Technology

The transfer of technology to developing countries has been and continues to be one of the necessary mechanisms through which a country may advance their industrialization process that in return will foster their ability to have the necessary technology to deal with the AIDS pandemic.⁵⁹ However, as in the case with foreign direct investment, the implications of IPRs on advancing technology transfer remains unclear. On one hand, IPRs may help create favorable conditions that allow the transfer to take place. But on the other hand, stronger protection means less imitation is likely to occur, which means patent-holders determine the extent to which their technology will be exploited. For this reason, it may become be harder to obtain protected technology and, once its obtained the royalties and payments are likely to be higher, thus leaving developing countries with little bargaining power and fewer funds available for local R&D. Finally, despite the difficulty in determining the impact that IPRs may have on technology transfer, it may be noted that policies and measures affecting the access to technology has become more restrictive during the past three decades and could be reinforced with the higher level of IPRs established in TRIPS.⁶⁰

3.4 HIV/AIDS Drug Pricing and Patent Protection

One of the most controversial aspects of the pharmaceutical industry has been the pricing of medicines and subsequently the above-normal profitability of drug firms. As drug prices have been on the rise during the last three decades, there has been an increased amount of attention on the corporate accountability of the pharmaceutical industry. In the USA, hearings into drug pricing have been held in Congress for over thirty years due to

⁵⁸ South Centre. The TRIPS Agreement: A Guide for the South. Geneva: South Centre, 1997, 35.

⁵⁹ Correa, Carlos. Intellectual Property Rights, the WTO and Developing Countries. London: Zed Books, 2000.

⁶⁰ South Centre. The TRIPS Agreement: A Guide for the South. Geneva: South Centre, 1997, 35.

high uncontrolled drug pricing.⁶¹ The debates surrounding the pharmaceutical industry in the USA have now moved into the international arena with the implementation of TRIPS. Today TRIPS is one of the most intensely debated international agreements because it allows for AIDS drugs to be included in intellectual property rights, thus granting the pharmaceutical manufactures monopoly power. This restricts other companies to market and sell cheaper, alternative “generic” versions of the drug at substantially lower prices.

Prior to implementing TRIPS, many developing countries that had restricted drug patents had been able to produce and market generics reducing the costs of AIDS medicines from \$10,000 to \$200 in some parts of the world.⁶² Once TRIPS becomes fully implemented, the pharmaceutical industry will be able to eliminate the competition of generic production by protecting their patents through the inflexibility of patent protection. The lack of competition in the production of AIDS drugs then becomes the fundamental reason why the pricing of AIDS drugs has been able to remain so high. This is because TRIPS restricts the right of governments to allow the production, marketing and import of low-cost copies of patented medicines, thus restricting competition and increasing prices. The average price increases in developing countries may range from 200-300 per cent and even higher for some essential medicines.⁶³

Moreover, these highly profitable and powerful research-based pharmaceutical companies currently own over 97% of all patents. And while TRIPS allows a certain degree of flexibility in its interpretation of when national health emergencies allow developing countries to acquire or produce cheaper drugs, these countries are usually subjected to the parallel forces of the pharmaceutical industry and developed world that threaten bilateral trade sanctions or force the countries into expensive WTO dispute panels.⁶⁴ For this reason, the compulsory licensing of generic drugs and other flexibilities in TRIPS has not been an option for most developing countries. At the same

⁶¹ Schweitzer, Stuart. Pharmaceutical Economics and Policy. New York: Oxford University Press, 1997, 8.

⁶² Panos Institute. Patents, Pills and Public Health. London: The Panos Institute, 2002, 2.

⁶³ OXFAM. “Patent Injustice: How World Trade Rules Threaten the Health of Poor People.” Oxfam Great Britain, 2001. 3.

⁶⁴ Cheru, Fantu. “Debt, Adjustment and an Effective Response to HIV/AIDS in Africa.” Third World Quarterly. 23:2 (2002), 307.

time, the burden of TRIPS falls heaviest on developing countries, since most drugs in developed countries are paid for by insurance, while most people in developing countries are not covered by insurance and must purchase the drug out of their own pockets. This forces those who least can afford it to spend the highest proportion of their income on medicinal drugs. This is exemplified by The Panos Institute, who explains that the cost of an AIDS inflicted tuberculosis treatment represents income from 500 working hours in Tanzania, 100 in Zimbabwe, 20 in Thailand and 1.4 in Switzerland.⁶⁵

The price of medicines is a critical factor in determining the public health of a country in both rich and poor countries. Yet, it is the areas where poverty is most perverse and households have limited budget resources that face the gravest threat from the rising prices of patented drugs. Because generic drug companies are able to produce low-cost equivalent products at a fraction of the costs associated with patented brands, they provide an important source of drugs to low-income populations. Some countries with highly sophisticated generic industries like Thailand, India, Egypt and Brazil have been able to reduce their dependence of imported patented medicines while also developing their capacity to export them. This has helped regions like sub-Saharan Africa, where the majority of essential medicines are imported from generic suppliers and are usually available at prices ranging between one-fifth and one-tenth of the costs of patented medicines.⁶⁶ In developed countries like the USA, the market share of generic drugs has increased from 19% in 1984 to 43% in 1996. Of these generic drugs, their prices are typically 25 to 50% less expensive than the patented drugs in the market.⁶⁷ The diagram on the next page illustrates the dramatic difference between patented and generic AIDS medicines between different countries. As this diagram shows, generic drug competition is a critical factor in reducing patented prices, however it can not be the only strategy used since newer drugs are not always immediately available in generic forms.⁶⁸ In the end, if the pharmaceutical industry does not effectively follow a systematic, transparent

⁶⁵ Panos Institute. "Patents, Pills and Public Health." London: The Panos Institute (2002), 4.

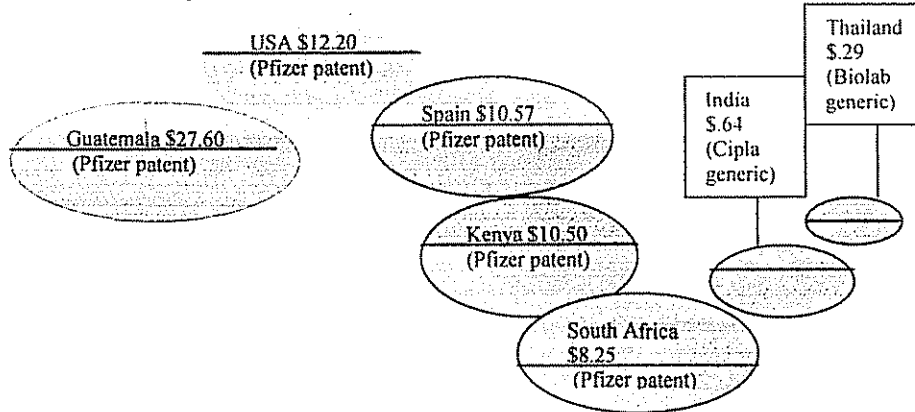
⁶⁶ South Centre. "Cut the Cost: The WTO and Drugs: The Rules are Loaded against the Poor." <<http://www.southcentre.org/papers/patent/patentinjustice-04.htm>> July 13, 2003, 6.

⁶⁷ Bollier, David. *Silent Theft* New York: Routledge, 2003, 167.

⁶⁸ Medecins Sans Frontieres. *Untangling the Web of Price Reductions* <www.accessmed-msf.org>, May 2003, 5-7.

approach for drug pricing, solutions regarding the problem of access for AIDS medicines will not be easily found or implemented.

Cost of daily dose of patented vs. generic fluconazole*, June 2000



*Fluconazole is an anti-fungal drug communal used against oral thrush and cryptococcal meningitis, both of which affect people with HIV⁶⁹

3.5 Post-TRIPS Options for Developing Countries for Increasing Access to Affordable Medicines

Since the development of TRIPS, many developing countries have focused on finding acceptable interpretations of the agreement that may help increase access to drugs.

Developing countries have implemented public health policy tools such as compulsory licensing, parallel imprinting and price controls, in order to help weaken the effects of the TRIPS agreement on drug supplies in developing countries. This section will explain these different options.

3.5.1 Compulsory Licensing

Compulsory licensing is a tool that allows a third party to make, use or sell a patented invention without the patent owner's consent. Compulsory licensing has been used historically for some of the most-prescribed drugs around the world as a way to combat monopoly power over pricing. For example, in the 1970's the prices of Valium, which was one of the world's best-selling drugs, fell from \$42 to \$4.10 per 1000 units in Canada due to compulsory licensing and in Germany, the producer of Valium, Librium, was

⁶⁹“AIDS/The Facts.” New Internationalist 346, June 2002, 18-19.

challenged in court for abusing their monopoly power over prices.⁷⁰ Today compulsory licensing is permitted in Article 31 of the TRIPS agreement in the case of national health emergencies.

While compulsory licensing provides a concrete option for the governments of developing countries to implement the provisions of TRIPS in a manner that is consistent with developing objectives and public health concerns, there are some limitations involved. The main limitation is that a country must first have a reasonably sophisticated pharmaceutical industry to produce the medicines and then they must also be able to achieve economies of scale to keep the prices down to affordable levels. Many developing countries are unable to achieve either of these abilities.⁷¹ For this reason, if the ability to import a cheaper generic version is essential.

3.5.2 Parallel Importing

When a patented product is sold at a lower price in another country, governments can allow 'parallel imports' from that country in order to take advantage of the differences in pricing, if this option is found within their national legislation. Parallel importing is often dependent upon compulsory licensing. For example, India is a country that practices compulsory licensing of certain drugs in order to export to countries that do not have manufacturing capacities of their own. In this context, parallel importing can provide developing countries a much needed alternative source of medicine so they are not forced to be dependent on the supplies coming from developed countries.⁷²

While parallel importing has been used as a public health safeguard mechanism to increase access to lower priced drugs, there are serious limitations involved. One is that pharmaceutical companies may implement uniform pricing globally, which would be at the highest possible price. Also, information on the market prices of medicines is usually difficult to obtain. And finally, if governments are unable to import generic-equivalent

⁷⁰ Scherer, F.M and Jayashree Watal. "Post Trips Options for Access to Patented Medicines in Developing Countries." *Journal of International Economic Law* (2002) 917-919.

⁷¹ Oxfam. *Patent Injustice* Great Britain: Oxfam, 2001, 23.

⁷² Cullet, Philippe. "Patents and Medicines: The Relationship between TRIPS and the Human Right to Health." *International Affairs* 79 (2003) 154.

medicines, the protection against monopoly pricing will probably be weak.⁷³ Yet, despite these limitations, parallel importing has been widely used by both developed and developing countries to circumvent price differences. In the UK alone, parallel imports coming from within the European Union make up about twelve percent of all prescriptions since drug prices are higher in Britain and in other European countries. Parallel importing then reduces the profit margin gained by the research pharmaceutical companies, which in return has led the pharmaceutical industry to lobby persistently for developing countries to prohibit parallel importing. Although this prohibition creates a barrier to international trade, the TRIPS agreement has allowed the ban, which shows the clear bias of the WTO towards corporate interest.⁷⁴

3.5.3 Differentiated Pricing

Some pharmaceutical companies engage in a certain form of price discrimination, which is often called differentiated pricing, in order to help reduce the high costs of patented drugs in developing countries. This form of discriminatory pricing called Ramsey-Baumol-Bradford Pricing, allows firms to set drug prices according to a diversity of markets with different income and demand levels, which allows firms to be most profitable by recovering the fixed costs involved, while maximizing consumer surplus.⁷⁵ Using differential pricing, prices are not based on the costs of production but rather on what the consumer will and can pay.⁷⁶ Since this form of pricing takes into account social and economic conditions it has the potential to be beneficial for developing countries especially since the developing world is not the primary source of pharmaceutical profits. For this reason, differential pricing has long been considered to be the 'most efficient' solution for corporations. However, there are many problems with price discrimination as it does not guarantee universal access and poses risks of intensifying parallel trade between states. Parallel importing occurs when prices are set higher in one country than in others. This means wholesalers in a low-price country will

⁷³ South Centre. "Cut the Cost: The WTO and Drugs: The Rules are Loaded against the Poor." <<http://www.southcentre.org/papers/patent/patentinjustice-04.htm>> July 13, 2003, 3.

⁷⁴ *ibid.*

⁷⁵ Scherer, F.M and Jayashree Watal. "Post Trips Options for Access to Patented Medicines in Developing Countries." *Journal of International Economic Law* (2002), 925-928.

⁷⁶ Cohen, Jillian and Patricia Illingworth. "The Dilemma of Intellectual Property Rights for Pharmaceuticals." *Developing World Bioethics* 3:1 (2003), 37.

divert their supplies through trade to countries that have higher prices, thus undermining the manufacturers attempt to maintain high prices.⁷⁷ And since the use of parallel importing is permissible under the TRIPS agreement and is employed by many countries, many pharmaceuticals have become less willing to engage in differential pricing.

Moreover, by dividing markets and setting prices according to the willingness to pay for drugs, the pharmaceutical industry will still be working with the ultimate aim of profit maximization within monopoly control of the market. This has led to price differences of several hundred percent between countries, such as Thailand and South Africa, and even European and East African countries, where Africa continues to be the worst off.⁷⁸ Also, there is a no uniform system determining pricing. In reality, each pharmaceutical industry has defined their own unique series of terms and criteria. For example, Merck uses criteria related to resources (Human Development Index) and epidemiology (HIV/AIDS prevalence) to determine national eligibility, which theoretically includes nearly 120 countries. Whereas, GlaxoSmithKline uses the classification of Least Developed Countries and the geographical classification of sub-Saharan countries, which then includes a total of 63 countries.⁷⁹ Another problem with the current implementation of differential pricing is that many drug companies, apart from Merck and Roche, do not have policies for countries that are not included in sub-Saharan Africa or classified by the United Nations as a Least Developed Country. Thus, a company like Bristol-Myers Squibb provides discounts to specific purchasers in sub-Saharan Africa but not in Central America, where prices must be negotiated by a case-by-case basis. Finally, eligibility of reduced prices varies according to each company's discretion. So even when one country may be eligible for cheaper drugs, not all institutions within the country may be eligible for the discounts.⁸⁰

⁷⁷ Scherer, F.M and Jayashree Watal. "Post Trips Options for Access to Patented Medicines in Developing Countries." *Journal of International Economic Law* (2002), 925-928.

⁷⁸ Bank, Helene. "Differential Pricing and Politics of Health Development." *Third World Network* 3.

⁷⁹ Medecins San Frontieres. *Untangling the Web of Price Reductions* <www.accessmed-msf.org>, May 2003, 5

⁸⁰ *ibid.*

Differential pricing continues to be one of preferred practices of the pharmaceutical industry, especially in regards to making some essential medicines in developing countries more affordable. In the past, Ramsey pricing has often been used to increase the access of many vaccines. However, if differential pricing is to be an effective option for developing countries, its problems must be addressed. Regional pricing may be looked upon as a solution to decrease the amount of parallel trade. Also, in order to ensure that developing countries can afford the prices charged, it has been proposed by Cohen and Illingworth that the World Bank or an independent actor assist the industry and states by acting as a broker between them by negotiating an equity-pricing system.⁸¹ An equity-pricing system would take differential pricing a step further by giving the pharmaceutical industry an even greater role in corporate social responsibility by providing medicines to the neediest.

3.5.4 Drug Donations

During the past two decades, many pharmaceutical corporations have participated in corporate philanthropy through large scale drug donations to developing countries. In 1998, four drug companies were listed as being the leading corporate philanthropists in the USA. Only eleven years earlier, Merck began to set the example of philanthropic behavior, when it decided to donate rather than sell its Ivermectin drug, which was effective in preventing river blindness and over the next decade the donated drug treated over 25 million people in developing countries.⁸² However, these philanthropic acts on such a scale are atypical. As Merck's CEO, Raymond Gilmartin explains, "Giving our medicines away in general is an unsustainable and unrealistic answer because, at the end of the day, we must earn an adequate return on our investment in order to fund future research."⁸³ Thus, the pharmaceutical industry must have incentives to initiate or participate in large scale drug donations.

⁸¹ Cohen, Jillian and Patricia Illingworth. "The Dilemma of Intellectual Property Rights for Pharmaceuticals." *Developing World Bioethics* 3:1 (2003), 40.

⁸² Scherer, F.M and Jayashree Watal. "Post Trips Options for Access to Patented Medicines in Developing Countries." *Journal of International Economic Law* (2002), 934.

⁸³ qtd. in Godrej, Dinyar. "The Great Health Grab." *New Internationalist* 362 November 2003, 5.

One important factor involved in the pharmaceutical industry's decision to donate drugs revolves around tax refunds. Looking closely at US pharmaceutical companies' impressive history of drug donations to developing countries, shows that many of the contributions have been compensated through US tax returns, which provides sufficient tax savings that entail minute to no out of pocket costs for the drug manufacturers.⁸⁴ Doctors without Borders claims that these tax deductions mean that drug donations cost the public sector of the donor country more than four times than other vehicles that attain the same results, such as differential pricing or the purchase of generics. The statistics also show that donor companies do not have real incentives to lower its prices to a more affordable level for the developing world, even when its real manufacturing costs may permit it. Thus, the current system of incentives actually encourages drug donations over the implementation of better policy options that would be more sustainable and less costly to the public.⁸⁵

While drug donations are not the solution for developing countries access problems, they are necessary and welcomed in certain situations, such as when its restricted to a particular region or the treatment or cure can be effective in a few easy doses.⁸⁶ Drug donations do have an important role in ensuring that the poorest of the poor who are unable to purchase drugs on their own are not neglected. Thus, the pharmaceutical industry should recognize the limits of drug donations as an effective solution, but also acknowledge that drug donations at times are essential for developing countries.

3.5 Doha Declaration and Beyond

In November 2001, the WTO's highest governing body, the Ministerial Conference issued a pronouncement that said TRIPS members may interpret their obligations in a manner that contributes to and does not work against their health policies. This ministerial pronouncement of intent, generally referred to as the Doha Declaration, is one of the most significant development since TRIPS, as it confirms the legitimacy of

⁸⁴ Scherer, F.M and Jayashree Watal. "Post Trips Options for Access to Patented Medicines in Developing Countries." 934.

⁸⁵ Panos Institute. Patents, Pills and Public Health Report 46, London: The Panos Institute, 2002, 16.

⁸⁶ *ibid.*

measures developing countries can use when trying to deal with health emergencies. This means public health needs can be the normative lens in which the TRIPS statutes are to be read and interpreted. The Doha Declaration of intent was finally amended into the TRIPS agreement on August 30th, 2003 as the WTO set out the terms on which countries can export to least developed countries cheaper, generic versions of patented drugs for HIV/AIDS.

Unfortunately, the victory of Doha is far from complete in promoting a balance between pharmaceutical patents and the problems of access. One problem is that while there is now an international consensus that these countries will not be questioned in terms of TRIPS obligations, Doha obliges countries to work within an exceptions framework rather than opening up new avenues to solve health emergencies.⁸⁷ By not amending TRIPS to include principles in favor of the access of drugs in the main provisions of the agreement, developing countries are forced to continue to explore the exceptions in order to find acceptable interpretations that have uncertain outcomes. Another problem that critics have pointed out is that the resolution is based on the same declaration that the European Union originally opposed because it did not think drug access would be made any easier for developing countries.⁸⁸ This latest agreement may in fact limit the flexibility previously allowed within TRIPS since it limits the grounds for using the exception of a health emergency to only three main diseases: HIV/AIDS, tuberculosis, and malaria. Also, there are several problems that remain in TRIPS, such as how to prevent the U.S. from using silent diplomacy, which at times threatens trade sanctions or is used in the negotiation of national and regional agreements that go beyond TRIPS.

Lastly, there is the production-for-export problem in which WTO members without sufficient manufacturing capacities in the pharmaceutical sector will not be able to make effective use of compulsory licensing that is granted under the TRIPS agreement. In many of the countries where the HIV/AIDS burdens are the highest, the governments lack the capacity to manufacture complex medicines on their own and can not import

⁸⁷ Cullet, Philippe. "Patents and Medicines." *International Affairs*. 79 (2003), 154.

⁸⁸ Raghavan, C. "Medicines won't be cheaper under TRIPS and public health decision." Geneva: Third World Network, 31 Aug. 2003.

them on their own since Article 31(f) of the TRIPS agreement requires that a product manufactured under a compulsory license be supplied primary to the licensee's domestic market. While the Doha Declaration helped to address some of the problems between TRIPS and the promotion of public health, there continues to be problems that need to be addressed. For this reason, the implementation of corporate social responsibility in the pharmaceutical industry has faced increased gravity and importance in the global fight against AIDS and inaccessible drug prices.

Chapter Four: Implementing Corporate Social Responsibility within the Pharmaceutical Industry

This chapter examines the response of the pharmaceutical industry in regards to improving the access to HIV/AIDS medicines to marginalized societies. The first section will discuss the arguments given by the industry's critics as to why the pharmaceutical industry needs to promote CSR. Next, it will analyze how the pharmaceutical industry has implemented CSR as a way to solve the problem of access. Finally, it will look at the problems that have arisen in their CSR approach.

4.1 Arguments for CSR within the Pharmaceutical Industry

Many critics of the pharmaceutical industry believe that the access to essential medicines in the developing world has been compromised by high prices and unprincipled behavior by pharmaceutical corporations. These critics claim that the exorbitant profits, innovation deficit and strong lobbying tactics used by the industry are reasons enough for the pharmaceutical industry to surrender profits, engage in more altruistic R&D, and help promote global public health through a more active implementation of CSR practices. This section will explore these arguments in order to understand the current approach the pharmaceutical industry has taken in CSR.

4.1.1 Exorbitant Profits

While people continue to suffer from AIDS related illnesses in the developing world, the pharmaceutical industry has grown in value by over 700 percent during the last two decades.⁸⁹ Today, the combined worth of the top five global drug companies is twice the combined GDP of all sub-Saharan Africa.⁹⁰ The pharmaceutical industry also has a much higher level of profitability that is approximately eight times the amount earned by other Fortune 500 industries. This is illustrated by the top ten drug companies to make the Fortune 500 list in 2001; these companies earned an average profit of 18.5 cents for every dollar of sales compared to the Fortune 500 median profit margin of 2.2 cents.⁹¹ And when the profits of the other Fortune 500 corporations took a 53 per cent dive in 2001,

⁸⁹ Oxfam, Save the Children and VSO. [Beyond Philanthropy](#). Oxford: Oxfam, 2002. 7.

⁹⁰ Shah, Anup. "Corporations and Medical Research." 2003

<<http://www.globalissues.org/TradeRelated/Corporations/Medical..28>> May 2003, 3.

⁹¹ Public Citizen's Congress Watch. "Pharmaceuticals Rank as Most Profitable Industry, Again." 17 April 2002, http://www.citizen.org/documents/fortune500_2002report.PDF. 10 June 2003.

the pharmaceutical corporation's profits went up by 32 per cent, bringing in the largest legal profits of any industry.⁹²

Today there are approximately 29 different drugs being used to treat HIV/AIDS, with each of these 'blockbuster' drugs bringing in sustained revenues of over \$1 billion in annual sales.⁹³ Despite the high profit margins that the blockbuster medicines have brought in, many pharmaceuticals companies fight for monopoly control of the drugs once patent protection expires. Some of the tactics used by the pharmaceuticals have been citizen petitions, lobbying, court challenges, and at times paying generic companies to delay product marketing. All of these tactics work to make generic protection more difficult with the hopes of delaying production when the patented drugs expire, thus sustaining the pharmaceutical company's profit margins. The pharmaceutical industry will only continue to strengthen these tactics, when considering that over the next five years, the patents of 20 blockbuster drugs with combined sales of over 20 billion will expire.⁹⁴

4.1.2 Innovation Deficit

Another reason why critics of the pharmaceutical industry are pushing for the industry's implementation of CSR is that the pharmaceutical industry has not invested the R&D resources necessary to produce the essential medicines and vaccines that are necessary developing countries. The main reason for this is that the introduction of new drugs to the market is a very expensive process. And just like any private investor, large pharmaceutical companies gear their research towards the markets and drugs that are likely to generate the largest profit. As a consequence, this eliminates the needs of developing countries that are burdened with poverty and low incomes, since the potential economic return is too small to justify investment. For this reason, the pharmaceutical industry prefers to allocate the majority of its R&D budget for chronic, ongoing medical conditions of the developed world as opposed to cures and vaccines that would largely

⁹² Godrej, Dinyar. "The Great Health Grab." *New Internationalist* 362, November 2003, 3.

⁹³ Public Citizen's Congress Watch. "Pharmaceuticals Rank as Most Profitable Industry, Again." 17 April 2002, http://www.citizen.org/documents/fortune500_2002report.PDF. 10 June 2003.

⁹⁴ Bollier, David. *Silent Theft*. New York: Routledge, 2003, 168.

help the developing world. That is why only ten percent of all R&D is being directed towards the illnesses that make up 90 per cent of the global disease burden.⁹⁵

However, many critics of the pharmaceutical industry argue that this is unfair as the industry continues to advocate for patent protection in developing countries as the means to increase R&D budgets. The industry claims that the increase in funding will then lead to an increase in the development of drugs related to the needs of developing countries. Yet, an examination of the industry's spending shows that this argument is questionable as there is a large discrepancy between the spending on R&D and the global distribution of diseases. This discrepancy is apparent by the World Health Organization's conclusion that of the 1,223 new chemical patents developed between 1975 and 1996, only 11 were for the treatment of tropical diseases.⁹⁶ Additionally, many of the important drug breakthroughs in the past fifty years have been initiated by the US National Institutes of Health and other government funded research. In fact, government funded research played an essential role in creating a variety of HIV/AIDS related drugs such as: AZT, ddI, ddc, d4T, Ziagen and Norvir.⁹⁷ The US government continues to be a key actor in the funding and developing of new drugs and vaccines that are directed towards the developing world. Once the new drug is developed, the government then sells the patent and its property rights to the pharmaceutical industry for the marketing and selling of the drug.

So what does the pharmaceutical industry spend its R&D budget and profits on? In general, pharmaceutical companies spend about 80% of its R&D budgets on "copycat" and "me too" drugs, which create drugs that are slightly different from existing drugs, but at the same time are innovate enough to obtain patent protection.⁹⁸ Besides these drugs that are usually developed and marketed towards the world's affluent societies, the amount of funding given to R&D is disproportionately minute compared to the amount of money being spent in other non-R&D areas. For example, Big Pharma tends to allocate

⁹⁵ Oxfam. *Patent Injustice* Great Britain: Oxfam, 2001, 39.

⁹⁶ Cullet, Philippe. "Patents and Medicine." *International Affairs* 79 (2003), 142.

⁹⁷ Bollier, David. *Silent Theft*. New York: Routledge, 2003, 163 and 166.

⁹⁸ Joseph, Sarah. "Pharmaceutical Corporations and Access to Drugs." *Human Rights Quarterly* 25 (2003), 434.

two or three times more on marketing than on R&D of new drugs.⁹⁹ Some examples of how the R&D spending compares to marketing levels in shown on the chart below:

R&D vs. Marketing Spending by Pharmaceutical in 2001¹⁰⁰

Company	% of Revenues Spent on Marketing/Advertising/Administration	% of Revenues Spent on R&D
Merck	13	5
Pfizer	35	15
Bristol Myers Squibb	27	12
Abbott Laboratories	23	10
Wyeth	37	13
Pharmacia	44	16
Eli Lilly	30	19

These large marketing budgets show that many pharmaceutical companies could lower drug prices without real lost to their R&D expenditures.

4.1.3 Pharmaceutical Lobbying

Corporate lobbying that has helped sacrifice public health for private profit. In the USA, the pharmaceutical industry has had an enormous amount of influence over the politics of international trade and intellectual property rights. Each year, the leading pharmaceutical trade group, the Pharmaceutical Research and Manufactures of America (PhRMA) spends millions of dollars lobbying Congress and state legislatures to fight against price controls and promote patent rights in international trade negotiations. They also have had an unwarranted amount of political influence on the foreign policy of the US government, which has contributed to the threatening of trade sanctions against Dominican Republic, Thailand, and South Africa. In general, PhRMA and other pharmaceutical lobbyists have become significant in the fact that they have been able to advance their own interests

⁹⁹ Joseph, Sarah. "Pharmaceutical Corporations and Access to Drugs." *Human Rights Quarterly* 25 (2003), 433.

¹⁰⁰ Panos Institute. "Patents, Pills and Public Health." London: The Panos Institute (2003), 6.

above the interests of public health, while also threatening the credibility of multilateral institutions, like the WTO.

In the USA, the main pharmaceutical lobbying group, PhRMA, has a board composed of representatives from the pharmaceutical giants, such as Pfizer, GW, Novartis, Johnson and Johnson, Aventis, Merck and Bayer.¹⁰¹ With each research-based pharmaceutical company paying dues, PhRMA has an annual budget of approximately \$150 million, which also helps to subsidize “like-minded organizations” and hires economists to promote their agenda through op-ed articles and monographs. While PhRMA has built up a diverse network of lobbyists with access to both political parties, their power has been described by Democratic Senator Richard J. Durbin of Illinois as “a death grip on Congress.”¹⁰² In Europe, the main pharmaceutical lobbying group is IFPMA, the International Federation of Pharmaceutical Manufacturers Associations, which also holds great lobbying power.

One of the most important lobbying efforts the pharmaceutical industry has played a role in was the creation and development of the TRIPS agreement. The main reason the pharmaceutical industry was a key supporter of TRIPS was because of the enormous amount of money the industry loses from patent infringement. It has been documented that the problem of patent infringement caused US drug companies to lose \$1.5 billion of an estimated \$28.8 billion in overseas sales due to inadequate patent protection in just three countries; Brazil, Argentina and India.¹⁰³ Thus, by working to prevent the manufacturing of illegal copies of patented drugs, many pharmaceutical companies were able to control drug prices in many developing countries in order to ensure profit. PhRMA also lobbied against allowing for flexible interpretations of the TRIPS agreement to safeguard public health. After the Doha Declaration was developed, the *Guardian* newspaper reported that “America’s drug industry has fought tooth and nail to impose the narrowest possible interpretations of the Doha declaration, and wants to restrict the deal to drugs to combat

¹⁰¹Oxfam. *Patent Injustice*. Great Britain: Oxfam, 2001, 26.

¹⁰²Pear, Robert. “Drug Companies Increase Spending to Lobby Congress and Governments.” *The New York Times*. 1 June, 2003.

¹⁰³Schweitzer, Stuart. *Pharmaceutical Economics and Policy*. New York: Oxford University Press, 1997, 133.

HIV/AIDS, Malaria, TB and a shortlist of other diseases unique to Africa” rather than all developing countries, which the WTO had originally agreed upon.¹⁰⁴

The pharmaceutical industry also spends a great deal on promotional spending for their lobbying efforts. The US pharmaceutical lobbyists spent 4.2 billion in 1997, which was the same amount Africa spent in of drug sales that year. For example, Pfizer has more employees working in the marketing department than the number of staff working in all of the WHO. Also, Merck joined the US government on a trip to Brazil in 2000 to help influence the Brazilian government to end its legislation that would help increase access to AIDS drugs.¹⁰⁵ When the government of Brazil remained adamant on treating its citizen’s afflicted with AIDS through generic ARVs produced domestically, the US government defended a US drug company involved by filing a complaint with the WTO’s Dispute Settlement Body over Brazil’s intention to “violate” patent rights.¹⁰⁶ In another legal dispute, 40 pharmaceutical companies from PhRMA and IFPMA sued the South African government for enabling the import of generic ARVs into South Africa with its Medicines Amendment Act of 1997, this case was eventually abandoned in April 2001 as a result of international pressure. In another dispute between GlaxoSmithKline and Ghana, AIDS patients in Ghana taking generic versions of Combivir had their drug supply cut off due to the lawsuit.¹⁰⁷ In conclusion, the pharmaceutical industry continues to be actively involved in lobbying US and European politicians through generous campaign contributions and public relations resources. Through their efforts to direct foreign policy and trade policy to serve their interests, the pharmaceutical industry has often placed their own interests above public health needs and put into questioning the sincerity of their efforts in CSR.

4.2 Incentives for CSR within the Pharmaceutical Industry

¹⁰⁴ Elliott, Larry and Charlotte Denny. “US wrecks cheap drugs deal.” The Guardian. 21 December, 2002

¹⁰⁵ Thomas, Caroline. “Trade Policy and the Politics of Access to Drugs.” Third World Quarterly 23:2 (2002), 257.

¹⁰⁶ Marwaan, Macan-Marker. “Generic-drug makers brace for battle with pharmaceuticals.” Third World Network 11 February, 2001 < <http://www.twinside.org/sg/title/brace.htm>> 13 April, 2003, 2.

¹⁰⁷ *ibid.* .

While the push from the pharmaceutical industry's critics is one reason why drug companies are taking a more active approach to CSR, there are other incentives that have influenced the industry to take a more philanthropic role of donating HIV/AIDS drugs to developing countries or making them available at lower prices. In particular, there are four incentives for CSR engagement; they are based on patent protection, the economic damage caused by AIDS, the ability to uphold the company's business reputation, and tax returns for charitable donations. The first incentive for the pharmaceutical industry to practice CSR is to protect their patent rights. By donating drugs, a company can reduce competition from generic versions entering the market and this also lessens the re-importing of generic versions into the markets of developed countries. Through patents, the company is also able to maintain monopoly pricing power. Another incentive that influences the pharmaceutical industry to respond to the AIDS pandemic through CSR is that the economic damage caused by HIV/AIDS will inadvertently hurt their future business. This is because limited economic growth lessens the ability of consumers in developing countries to afford other drugs. The third incentive is that good business equals good publicity. There has been an increased amount of pressure placed on the pharmaceutical industry by civil society who demands corporate accountability and a more active role to be taken in efforts to solve the AIDS problems. Finally, many pharmaceutical companies choose to implement CSR because of tax incentives offered for corporate charitable donations within the US and Europe. This incentive was discussed in more detail in Section 3.5.4 on drug donations.

4.3 The Implementation of CSR in the Pharmaceutical Industry

While the responsible behavior of all types of organizations has stimulated great debate and gained a high place on the public agenda, the pharmaceutical industry is one sector that has recently taken considerable steps to make CSR concerns a more integral part of their business. This section will give an overview of the pharmaceutical industry's implementation of CSR in order to analyze how committed the industry is to CSR and the extent that CSR can be an effective tool for reducing the price of AIDS drugs. In order to analyze the implementation of CSR in the pharmaceutical industry we must first look at

how the corporations within the industry describe CSR and then look at how CSR is being exercised through various policies and practices.

In general, most pharmaceutical companies use the name CSR when referring to this specific field of work. However, Oxfam, Save the Children and VSO recently conducted a survey that found out that only seven out of the top eleven companies had policy statements on CSR. Additionally, the majority of the companies did not even have policies regarding the access to medicines for developing countries. Only two of the companies, Novartis and GlaxoSmithKline (GSK) had addressed this problem, with GSK's *Facing the Challenge* being the industry's first attempt to comprehensively address the issues of access.¹⁰⁸ Besides incorporating the CSR name into their business, many companies continue to have different views on what CSR implies. While some companies, like GlaxoSmithKline, see corporate responsibility as an integral part of their business, others question their social responsibilities.¹⁰⁹ For instance, Bernard Lemoine, director-general of France's National Pharmaceutical Industry Association says: 'I don't see why special effort is demanded from the pharmaceutical industry. Nobody asks Renault to give cars to people who haven't got one.'¹¹⁰

In order to look at how the pharmaceutical industry has implemented CSR, two different actions of the pharmaceutical industry will be explored: pricing and joint public/private partnerships. While the industry has taken many other actions of CSR implementation, these are two of the areas that have received the greatest attention by the industry and public spotlight.

4.3.1 Lowering the Prices of HIV/AIDS Medicines

During the last two and half years, there have been major price cuts on antiretroviral drugs in the developing world, which has led prices to drop by over 85%. For example, GlaxoSmithKline, the world's largest maker of antiretroviral drugs has repeatedly cut

¹⁰⁸ Oxfam, Save the Children and VSO. *Beyond Philanthropy*. Oxford: Oxfam, 2002, 11..

¹⁰⁹ GlaxoSmithKline. *The Impact of Medicines: Corporate and Social Responsibility Report 2002*. <<http://www.gsk.com>> 10 April 2003.

¹¹⁰ qtd in. Godrej, Dinyar. "The Great Health Grab." *New Internationalist* 362, November 2003, 5-6.

prices for both developing and developed countries. In April 2003, they further cut the price of Combivir, a popular AIDS medicine that combines two drugs in one pill from \$1.70 a day to 90 cents a day, making the medicine roughly equivalent to some generic versions of AIDS drugs.¹¹¹ Other pharmaceutical companies have also responded with price cuts. For instance, Abbott, now offers to sell two of its AIDS drugs and HIV test “at no profit” to developing countries. Bristol-Myers Squibb responded by offering full transparency in its pricing for its “below cost” AIDS drugs, while also offering to raise funding for its Secure the Future program to \$115 million, and announced that “the patent for Zerit [d4T]...will be made available at no cost to treat AIDS in South Africa.” Or rather as a spokesperson for Bristol-Myers Squibb put it, “although we’re not actually relinquishing our rights to Zerit, if somebody in South Africa infringes on the method of use in our patent, we’re not going to object.”¹¹² Lastly, Merck has repeatedly lowered its Stocrin drug from its already lowered price of \$1.37 per day to 95 cents per day to the hardest-hit countries that have made individual agreements with Merck.¹¹³

However, the majority of these price cuts have not been enough, the lowered drug prices continue to be out of reach for the poor, while also remaining higher than the prices offered by generic firms. For instance, Bristol-Myers Squibb’s “below cost” drug remains at a price that is two times higher than that charged by generic firms.¹¹⁴ Even the generic industry has joined in challenging the research-based pharmaceutical industry to lower its AIDS medicines. During the past two years, Cipla, the Indian generic pharmaceutical company has been adamant on challenging the stance of the research-based pharmaceutical industry by offering to sell large quantities of generic HAART drugs to African countries from between \$255 per year to patients and \$600 per year to African governments. Cipla has also offered to sell its drugs to Doctors without Borders

¹¹¹ Abelson, Reed. “Glaxo Will Further Cut Prices of AIDS Drugs to Poor Nations.” The New York Times April 28, 2003.

¹¹² qtd. in “Taking the poisoned pill.” Mallenbaker.net 27 May 2003
<<http://mallenbaker.net/csr/CSRfiles/aids/html>> 1 June 2003, 1.

¹¹³ Consumer Project on Technology. “Offers of Price Reductions for HIV/AIDS Drugs.” 2003
<<http://www.cptech.org/ip/health/pcuts.html>> 4 October, 2003.

¹¹⁴ Consumer Project on Technology. “Offers of Price Reductions for HIV/AIDS Drugs.” 2003
<<http://www.cptech.org/ip/health/pcuts.html>> 4 October, 2003.

for distribution, since the organization had 'little progress' on previous agreements made that had promised drug discounts from five pharmaceutical companies.¹¹⁵ Furthermore, in October 2003, the Clinton Foundation made a landmark AIDS deal by negotiating further price reductions with four generic drug companies: Aspen Pharmacare Holding Ltd. of Johannesburg and Indian companies Cipla Ltd., Ranbaxy Laboratories Ltd. and Matrix Laboratories. These four companies agreed to supply a triple combination of AZT/3TC and nevirapine for \$132 a year to four African nations and nine Caribbean states, with plans to target 1.5 million people by 2008. The companies were able to cut the prices of the medicine by cutting marketing and distribution costs since the treatments are well known and do not require advertising¹¹⁶ and by negotiating with Chinese manufacturers to lower the price of the raw materials needed to make the antiretroviral.¹¹⁷

In summary, the pharmaceutical industry's approach towards reducing the prices of AIDS medicines on an individually-negotiated, non-transparent, case-by-case basis is simply not enough in order to meet the needs of developing countries. Rather, the industry should take a systematic, global approach to pricing that recognizes the great economic differences between developing and developed countries, which could be formalized in a global tiered-pricing system.¹¹⁸ Also, the industry needs to provide a long-term commitment to sustaining low drug prices, increase flexibility in the interpretations of the TRIPS agreement in order to allow for generic competition and also expand their commitment to ensure that it reaches out to other diseases that afflict the developing world.

4.3.2 Joint Public Private Initiatives

The pharmaceutical industry has also been increasingly involved in a number of joint public private partnerships working to eliminate the effects of AIDS in the developing world. There are currently more than 50 separate public-private partnerships occurring

¹¹⁵ Macan-Marker, Marwaan. "Generic-drug makers brace for battle with pharmaceuticals." *Third World Network* 11 February 2001 <<http://www.twinside.org.sg/title/brace.htm>> 13 April, 2003, 1.

¹¹⁶ "Clinton Brokers Landmark AIDS Deal." *BBC News* 24 October 2003 <<http://news.bbc.co.uk>> 16 November 2003, 1.

¹¹⁷ Alcorn, Keith. "Clinton Foundation Secures Triple HIV Therapy for \$132 a year." *AIDS Map* 24 October 2003 <<http://www.aidsmap.com/news>> 16 November 2003, 1.

¹¹⁸ Oxfam, Save the Children and VSO. *Beyond Philanthropy*. Oxford: Oxfam, 2002,12.

around the world.¹¹⁹ These partnerships are where companies, public health and finance bodies work together to target a specific disease (such as HIV/AIDS) common to the developing world. In these partnerships, companies help cover R&D, disease prevention or treatment, along with education, infrastructure and technical assistance or they help to donate drugs or provide price reductions on specific medicines. The industry has increasingly regarded the joint public private partnerships as the most effective action they can take in fulfilling its responsibility to increase access to AIDS medicines.¹²⁰ This can be seen in the responses of different companies. For example, Pfizer claims that ‘...the watchword should be partnership,’ and Novartis believes that ‘Joint Public Private Initiatives need to become the preferred working method and not merely exceptions.’¹²¹

Many joint public private partnerships have emerged in the past few years. One example of a partnership with UN agencies and other international institutions is the Accelerating Access Initiative (AAI). Within this program, companies have been supplying drugs to AIDS patients in some of the 80 poorest countries worldwide, with prices that are heavily discounted. Companies have also been donating drugs to help eliminate mother-to-child transmissions of HIV/AIDS.¹²² Another initiative is the Global Business Coalition on HIV/AIDS, which is an alliance of governments, civil society, and business working to combat AIDS. While these initiatives can be of critical value for the tackling of diseases that affect the poor, they alone are not always the most appropriate response from the industry. Oxfam, Save the Children and VSO have criticized many of the joint partnerships as being limited in scope and short-term in delivery, which make their benefits unpredictable and thinly spread. They also report that many partnerships can further marginalize populations, since many of them target countries or areas within countries that have health systems that are already strong and can deliver fast results.¹²³ Thus, drug companies must take a critical look at their CSR objectives to ensure that partnerships alone can be effective tools for increasing the access of drugs to the poor.

¹¹⁹ Bale, Harvey. “The Pharmaceutical Industry and Corporate Social Responsibility.” 2003 <<http://www.responsiblepractice.com/english/insight/ifpma/>> 18 August, 2003, 1.

¹²⁰ Oxfam, Save the Children and VSO. *Beyond Philanthropy*. Oxford: Oxfam, 2002, 16.

¹²¹ qtd in. *ibid*, 18..

¹²² Bale, Harvey. “The Pharmaceutical Industry and Corporate Social Responsibility.” 2003 <<http://www.responsiblepractice.com/english/insight/ifpma/>> 19 August 2003.

¹²³ Oxfam, Save the Children and VSO. *Beyond Philanthropy*. Oxford: Oxfam, 2002, 17.

4.4 An Analysis of the Pharmaceutical Industry's CSR Approach

The scale of the AIDS epidemic and its “insolvable” problems, has pushed corporations into moving beyond business as usual. And the pharmaceutical industry is one sector that has responded to a large extent by moving to adapt new terms of operation that it would probably never have considered before.¹²⁴ This in itself is commendable and should be acknowledged as a step in the right direction. The pharmaceutical industry has done a great deal in making patented drugs more accessible to the poor in the realm of discounting drugs to below cost price, by making donations, by increasing transparency, by implementing health programs and/or by working in joint partnerships. However, as much as the industry may do in this realm, it has continued to uphold their right to patent protection without any compromise on the legal status of their AIDS medicines. The hard lobbying efforts made by the pharmaceutical industry, the legal actions taken against the government of South Africa, and the unwillingness to make exceptions regarding compulsory licensing, etc. show the pharmaceutical industry's unwillingness to bypass patent protection and exemplifies the need for the industry to go a little further in its implementation of CSR.

While the pharmaceutical companies have responded to the intense international pressure placed on them by civil society to make AIDS drugs more affordable in poor countries, the prices for many of the originator drugs continue to be significantly higher than their generic equivalents. Generic competition continues to be the most reliable factor for reduced pricing, not voluntary discounts. Another problem with lowering prices is that the cuts are not universal, predictable or sustainable. This is because the eligibility for receiving lower prices remains at a company's discretion, even with a country eligible, not all institutions with the country are eligible. And the countries eligible vary according to region. Additionally, most pharmaceutical companies have not developed pricing policies for middle-income countries. Also, the price cuts have been limited to AIDS

¹²⁴ “Taking the Poisoned Pill.” [Mallenbaker.net](http://www.mallenbaker.net) 27 May 2003
<<http://www.mallenbaker.net/csr/CSRfiles/aids.html>> 1 June 2003, 2.

drugs, which shows that disease must first reach epidemic proportions and have global attention before the pharmaceutical industry reacts and lowers prices.

Another problem with the pharmaceutical industry's current implementation of CSR is that the industry continues to remain unwilling to adopt flexible interpretations of TRIPS. For example, Cambodia's legislation had adopted a law allowing Cambodia until 2016 to fully implement TRIPS as justified by the Doha Declaration. And while this interpretation of Doha was considered valid, US pressure in closed-door negotiations forced them to change their legislation to implement TRIPS by 2007 for their accession into the WTO.¹²⁵ This case demonstrates the industry's need to re-evaluate their lobbying efforts on shaping trade policies and how it may contradict its social responsibilities. The industry must also consider temporarily relaxing their patents protection as a useful step towards dealing with the AIDS epidemic. Finally, not all pharmaceutical companies have CSR policy statements and even fewer have policies regarding AIDS and the access to medicines for the poor.

In summary, the pharmaceutical industry has been taking steps in the right direction in its efforts to implement CSR. They have drastically cut the prices of AIDS medicines and helped increase access to certain populations; they have donated a great deal of medicines to developing countries, and have implemented joint public/private partnerships working to solve the AIDS pandemic. Yet, despite these actions, the industry remains far from creating a sustainable solution to the problem of access in developing countries. Thus, if the pharmaceutical industry is really committed to implementing CSR into its operations, it is necessary for the corporations to review and revise its objectives in order to prevent adverse impact on health and development.

¹²⁵ Medecins Sans Frontieres. Doha Derailed 2003 <<http://www.accessmed-msf.org>> 15 October 2003, 2.

Chapter Five: Conclusion and Recommendations: Balancing Relevant Interests

In this chapter, a discussion based on the research questions and problem is presented. The discussion is combined with conclusions that have been derived from the analysis in the previous chapters. Furthermore, a set of solutions and recommendations will be suggested for the pharmaceutical industry to strengthen and improve its CSR activities in the realm of the AIDS epidemic and obstacles to access.

5.1 Summary and Lessons Learned

This paper has addressed the problems behind increasing the access to HIV/AIDS medicines in the developing world and its relationship with the pharmaceutical industry and its policies of social corporate responsibility. Throughout the paper a series of key points emerged:

- AIDS is affecting the poorest in the world. More than 95% of new cases are occurring in developing countries and the majority of the sick are unable to benefit from the development of ARV drugs due to unaffordable prices.
- The possibility of an effective solution to increase access to AIDS medicines is being hindered by the provisions of the TRIPS Agreement, which in practice often gives patent rights priority over public health claims.
- Patents and profits are closely interlinked, since patents allow pharmaceutical companies monopoly pricing power.
- The research-based pharmaceutical industry is immensely powerful. Their pricing policies and lobbying efforts have often made them adversaries rather than allies to people living with AIDS¹²⁶
- The pharmaceutical industry has gone through considerable changes in its efforts to incorporate CSR into its policies and practices. The industry has taken significant steps to increase the access to AIDS medicines in developing countries through drug donation, the lowering of drug prices, and initiating joint public/private partnerships.

¹²⁶ Irwin, Millen, and Fallows. Global AIDS: Myths and Facts. Cambridge: South End Press, 2003, 189.

However, the industry continues to place the interests of the patent holders above developing countries' public health obligations.

These key points are essential in understanding the underlying question of to what extent the implementation of CSR in the pharmaceutical industry can help provide solutions to the problems of the AIDS pandemic. As seen in chapter three and four, limitations abound within the pharmaceutical industry's voluntary CSR initiatives. While, an increasing number of companies are embracing a CSR commitment to 'do the right thing,' this has usually meant doing that which is good for business and not necessary what is best for society. As seen in the pharmaceutical industry's CSR approach to the AIDS problem, the drug companies took significant first steps to relieve aspects of the problem, but did not actually eliminate the problem. The AIDS pandemic has shown how the costs of essential drugs in the developing world are becoming prohibitive as a result of the implementation of intellectual property rights for pharmaceutical products. Yet, the pharmaceutical industry has been slow to react or acknowledge that patent protection is not always in the best interests of developing countries.

In conclusion, if the implementation of CSR practices is to assist the pharmaceutical industry in efforts towards finding solutions to the pricing problem of AIDS medicines, the international community must also be involved and ask what role governments and civil society can play in helping to develop policy innovations that promote corporate accountability, while also helping to define norms and provide incentives for better corporate performance. Thus, an effective solution for the AIDS pandemic and the problems of access must be multi-faceted and represent an appropriate balance between all the primary interests at stake. These interests include the concerns of the sick and their need to have access to essential drugs, the interests in fostering an optimum level of pharmaceutical R&D that is useful for all consumers; and the interests of the pharmaceutical industry and its shareholders in making profits.¹²⁷ With this in mind, this paper challenges the pharmaceutical industry to adopt and implement CSR standards

¹²⁷ Joseph, Sarah. "Pharmaceutical Corporations and Access to Drugs." *Human Rights Quarterly* 25 (2003), 451.

balance their interests while also taking on a strengthened role in addressing the global AIDS pandemic.

5.2 Recommendations

Listed below are recommendations for the pharmaceutical industry and international community to implement in order to work towards a solution that balances the interests of the public and private sectors:

- 1. Develop a Global Convention on R&D:** James Love from the Consumer Project of Technology has argued for a global convention on R&D to replace TRIPS as it related to medicine by obligating countries to fund R&D according to their abilities and stage of development, through policy instruments that make sense for them.¹²⁸ A convention or fund could be developed that is dedicated to developing new medicines and vaccines for the infectious diseases that afflict developing countries.
- 2. Change TRIPS Agreement to safeguard public health:** The international community should amend the TRIPS Agreement so that development objectives are integrated into the intellectual property rights regime. The changes should strengthen the ability of developing countries to participate in compulsory licensing and parallel importing when needed. At the same time, the scope for legal challenges by patent holders should be limited.
- 3. Cut Costs of Essential Medicines:** Pharmaceutical Industry should cut the cost of key medicines in developing countries so they are affordable to the poor or they should allow the generic industry to provide for the poor.
- 4. Balance Public Health with Patent Claims:** The pharmaceutical industry should work to balance their patent rights with the public health needs in developing countries. They should exercise their CSR practices with respect to their patent claims, through CSR they should not seek to enforce patent claims on drugs that are essential to developing countries and they should also take a more

¹²⁸ Bank, Helene. "Differential Pricing and Politics of Health Development." Third World Network <<http://www.twinside.org.sg/title/politics.htm>> (2001) 2.

flexible approach with developing countries' interpretations of TRIPS to ensure that people come before profit.

- 5. Establish an International Fund to Subsidize Drug Purchases:** As recommended by Oxfam, the international community should commit to a level of funding that would subsidize drug purchases and delivery systems for the poorest countries. By providing long-term continued support, developing countries would no longer have to rely solely on sporadic drug donations by the pharmaceutical industry.¹²⁹
- 6. End Unfair Trade Policies:** Developing countries efforts to pursue legitimate strategies to secure affordable drugs should not be obstructed by the combined power of the pharmaceutical industry and the US government. The pharmaceutical industry should end lobbying efforts that allow the US to place unilateral pressure on countries to adopt patent legislation that is not in the public health interest and that is not legally required by TRIPS.
- 7. Provide Tax Incentives for Good Corporate Behavior:** Governments of developed countries could give tax breaks to pharmaceutical companies that donate patent rights or for the research and development of products that do not have reasonable financial returns. As this paper shows, US tax incentives on drug donations have promoted the US pharmaceutical industry to engage more in philanthropic practices. These tax incentives could be extended to the other areas in which developing countries would benefit from.
- 8. Assess the impact of Patents on Public Health in Developing Countries:** The next review of TRIPS should include a full assessment of its impact on the affordability and accessibility of medicines in developing countries. This assessment should then be taken into consideration by all WTO members to ensure that developing countries are on the same playing field as developed countries in regards to patent protection and public health.

¹²⁹ Oxfam. Patent Injustice. Great Britain: Oxfam, 2001, 10.

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