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ESSAY: PHARMACEUTICALS AND GLOBAL JUSTICE: BALANCING PUBLIC HEALTH AND INTELLECTUAL PROPERTY RIGHTS

by Marisa Morabito

I. INTRODUCTION

Patents and prices have had a detrimental impact on poverty and the spread of diseases such as HIV/AIDS which remains a significant issue globally, especially in South Africa. Hopkins states “The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), governed by the World Trade Organization, provides for stringent patent protection in the name of intellectual property rights. This international agreement has elicited public health concerns in developing countries, worried that they will be unable to access essential medicines as a result of increasing patented drug costs.”\(^1\) According to statistics from the Just Like My Child Foundation, HIV/AIDS in Africa are great in number.\(^2\) Statistics show that “to date, 17 million Africans have died of AIDS and 25 million Africans (many children) are infected with the HIV virus. HIV can be treated with modern medications, so long as those drugs are available and administered.”\(^3\) Statistics have shown that “18 million deaths per year – 50 thousand daily-are due to preventable poverty related causes...while one-third of the world’s population subsists on less than $2 per day and half of the world’s population in some of the poorest countries in Asia and Africa lack access to essential medicines.”\(^4\) Globally, there has been a constant struggle in balancing intellectual property rights with human health and poverty reduction. Crook reports that “the Joint UN Program on HIV/AIDS estimates that between thirty-four and forty-six million people around the world are living with the condition.”

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3 Just Like My Child Foundation, HIV/AIDS at 1.
4 Hopkins at 85-86.
While sub-Saharan African states have suffered the worst epidemics to date, the World Health Organization (WHO) predicts new outbreaks in North Africa, India, China, states in Central Asia, and the Baltic states.\(^5\) Crook describes that “anti-retroviral drugs do not reach the 90% of HIV/AIDS infected people living in the poorest 10% of the world’s countries. In South Africa, tens of thousands of people are dying every year because excessive prices are charged for life-saving anti-retroviral medicines. The worst is probably yet to come for South Africa, where lack of access to effective medication will facilitate the rapid spread of AIDS-related deaths.”\(^6\)

In South Africa, the Medicines Act was established in order for actions to be taken in order to promote public health in times of severe need, such as allowing for compulsory licensing. However, countries such as the United States have prevented this Act from being used to accomplish its purpose.\(^7\) For instance, the United States responded that the South Africa Medicines Act would violate IP rights and impact the economy by adversely affecting pharmaceutical companies.\(^8\) Hopkins states that “The heart of the debate is striking a balance between the rights to IP protection, championed by multinationals and developed countries, and the developing world’s right to health via affordable drugs in the face of extreme disease and poverty.”\(^9\)

The above outlined consequences of the prevailing policies regarding IP protection and pharmaceuticals is a result of a utilitarian economics approach. The utilitarian economics approach and the approach which pharmaceutical companies have expressed is that there is a need for strong patent protection in order to generate profits which will allow pharmaceutical

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\(^5\) Jamie Crook, Balancing Intellectual Property Protection with the Human Right to Health at 524.

\(^6\) Crook at 525.


\(^8\) Nagan at 178.

\(^9\) Hopkins at 84.
companies to further their research and innovation of medical drugs which will consequently be better for global health. For instance, utilitarian economic theory is based on the belief that there should be strong IP rights which are strongly enforced against those who infringe in order to incentivize people to innovate.\textsuperscript{10} Utilitarian economics is based on the premise that incentives will allow for a high amount of social goods.\textsuperscript{11} The utilitarian approach is based upon the premise that the creation and distribution of effective pharmaceutical products requires motivated individuals. In the absence of motivated individuals there will be no innovation and widespread distribution of critical pharmaceutical products. Therefore, the public good will not be served. Utilitarians want to protect scientific innovation as they believe that a lack of protection through the use of IP rights would cause there to be no incentive since others could pirate their inventions and products and profit without actually creating it.\textsuperscript{12} Utilitarians want to achieve the highest overall well-being and since pharmaceuticals will allow for the welfare of humans, IP rights and patents are necessary to protect their inventions and products of the inventors.\textsuperscript{13} The evidence suggests however, that the continued policy of IP rights as manifested in TRIPS does not result in the greatest good for the greatest number of people but even further is unjust and therefore morally wrong. The utilitarian approach has been deemed unjust. This is because the struggle with poverty has continued to have devastating impacts due to pharmaceutical companies who have charged excessive prices and fail to allow generic drugs to treat illnesses, including anti-retrovirals in order to treat HIV/AIDS.


\textsuperscript{11} Morrissey at 17.


\textsuperscript{13} Cernea and Uszkai at 215-216.
The approach to IP rights and global pharmaceutical industry thus requires a different philosophical, ethical framework. I would like to suggest a virtue and human flourishing approach which is based on human good and well-being and helping others to also be able to flourish by living ethical lives which parallels Nussbaum’s capabilities approach, a virtue ethics view. Virtue ethics is an ethical system based upon adherence to a principle. Virtue ethicists believe that there are “certain ideals toward which we should strive...[to allow] for the full development of our humanity” by looking at what humans can become. The virtue ethicist focuses on humans achieving their maximum potential while having virtues of compassion, generosity and courage. For instance, “a person who has developed virtues will be naturally disposed to act in ways consistent with moral principles. Virtue ethics emphasizes character formation and habits to foster positive improvements in the world. A virtuous person wants to behave well and looks at a circumstance and decides what is right and wishes to behave according to what is right. This view aligns with Nussbaum who takes a capabilities view which is based on the idea that well-being is “of vital moral importance [and]...individuals must have real opportunities to live well and to flourish as human beings. Nussbaum’s capabilities view looks at the important functions of a human being and looks at what institutions are doing for those capabilities. For example, functions and capabilities are set and then we observe whether intuitions are promoting human flourishing based on these principles.

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14 Morrissey at 47.
16 Velasquez at 1.
17 A virtue ethics approach to moral dilemmas in medicine, P Gardiner at 1, http://jme.bmj.com/content/29/5/297.long.
18 Velasquez at 2.
19 Gardiner at 1.
20 Morrissey at 47.
21 Morrissey at 47.
22 Morrissey at 48.
are not being met, we must try to change the institution’s policies to allow for human flourishing. Nussbaum’s capabilities approach explains what flourishing is and tries to achieve this flourishing worldwide. Based on this theory, IP rights “generate a material circumstance for a majority of the world in which we can’t maximally exercise our intellectual capacities, and thus we fail as a species to maximally flourish.” Therefore any further discussion of IP rights and the global pharmaceutical industry must proceed clearly focused on adherence to a moral principle; maximizing human flourishing.

Successful efforts in South Africa were only achieved when the policy became virtue/principle based. In the Minister of Health v. Treatment Action Campaign, the court ruled that the government breached the people’s right to have access to health care services when it prevented drug availability to pregnant women in order to stop mother-to-child HIV transmission. 2.4 million people have received free anti-retroviral treatment in 2013 which was a 1.4 million increase from 2009 while over 20 million people have been tested for HIV since the government created counseling and testing programs in 2010. South Africa’s goal is to have an extra 4.6 million people receiving anti-retroviral treatment within the next five years. Furthermore, South Africa has reduced the prices of anti-retrovirals and there was a tender to make one ARV pill which can be used once instead of having to take three pills two times per day which means there will be fewer pills used and consumed. Although there have been

23 Morrissey at 48.
24 Morrissey at 48.
25 Morrissey at 48.
26 Zivi at 180.
27 SA to expand HIV treatment program, 2014 at 1, http://www.southafrica.info/about/government/stateofnation2014e.htm#.UwN24P6A0eE.
28 SA to expand HIV treatment program at 1.
successes, the South African population continues to have the highest number of HIV/AIDS infected people globally as millions still lack access to ARVs.\textsuperscript{30}

The ongoing tension between the fight against poverty and IP rights continues to persist at the mercy of humans in poorer nations who are unable to afford medications to cure their illnesses and diseases which hinders maximum human flourishing and does not express good character. In her article “Common Ground: The Case for Collaboration Between Anti-Poverty Advocates and Public Interest Intellectual Property Advocates” Cantrell states that with intellectual property advocates, their focus is on the individuals rights to create, appropriate, and recreate.\textsuperscript{31} However, the tension between the fight against poverty and the protection of intellectual property rights is evident as the IP movement’s success is frequently at the expense of the poor.\textsuperscript{32} Cantrell continues to state that Martha Nussbaum’s virtue theory of human capabilities suggests that every person should have the ability to live a flourishing life yet the IP movement has placed limitations on what a person can do and be as a result of continued poverty.\textsuperscript{33}

Advocates of the anti-poverty movement have placed significant emphasis on the United Nations Commission on Human Rights which has determined that access to medicine is a human right.\textsuperscript{34} However, pharmaceutical companies have a great amount of control over the distribution and prices of medications. For instance, the World Trade Organization implemented TRIPS, an international treaty regarding intellectual property rights standards in order to allow for IP protection.\textsuperscript{35} The idea behind the TRIPS treaty was to give pharmaceutical companies an

\textsuperscript{30} Zivi at 182.
\textsuperscript{32} Cantrell at 423.
\textsuperscript{33} Cantrell at 428.
\textsuperscript{35} Crook at 530.
incentive to invent medications while being able to profit from the creation of pharmaceutical drugs. TRIPS provides for patent protection for twenty years from the time of filing. Proponents of intellectual property rights including intellectual property specialist Gerald Mossinghoff have explained:

"Effective patent protection at home and abroad is vitally important to the United States pharmaceutical industry. America's research-based pharmaceutical companies pour millions of dollars into the research and development of new technology every year. Whether this commitment can continue depends greatly upon the extent to which foreign governments allow innovators to be rewarded for their inventiveness, monetary investment, and intellectual labor. For the private sector pharmaceutical industry, which has been the primary source of new therapies for the past four decades, there is little incentive to provide an ever-increasing commitment to research unless there are reasonable expectations of financial return. Only effective patent protection provides the incentives necessary to enable pharmaceutical companies to commit the required resources."

IP rights proponents have argued that protection is essential for incentives to create. Furthermore, Hopkins explains additional arguments in favor of IP protection are the incentives due to the financial rewards as a lack of patents would make it hard for creators to recover their investments due to reverse engineering and knock offs which would result in fewer investments and less research to treat worldwide diseases.

However, this patent protection inflates prices more than one hundred times their cost which hinders humans worldwide from opportunity and from being able to have well-being so

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36 Lazzarini at 109.
37 Fisher and Syed at 672.
38 Hopkins at 85.
that they may flourish.\textsuperscript{39} It is significant to note the political power that pharmaceutical companies, especially in the United States, where lobbyists contributed millions annually. Although innovators should be rewarded, pharmaceutical companies should shift their focus to poorer nations in order to limit the spread of disease, allow those in poverty right to life and result in more trading partners by having a pricing scheme based on per capita income in order to allow medications and treatments to be available to poorer populations.

II. THE PROBLEM WITH DRUG INNOVATION

As pharmaceutical companies continue to invent drugs and medications there has been a continued focus on the rich which does not allow for maximum human flourishing as many people are left without access to essential medicines. Pharmaceutical companies have focused on the needs and wants of those living in wealthy companies while forgetting about those in poorer nations. For instance, Sunder states that “The dominant law-and-economics approach would rely on the market to spur creation but this leads to the appalling conclusion that drugs for baldness must be more important than drugs for malaria because the former enjoy a multi-billion-dollar market, while those who need the latter are too poor to offer much to save their own lives” as the focus of pharmaceutical companies has been on developing lifestyle drugs.\textsuperscript{40} This is because companies have more of an incentive to innovate where there is a wealthier market with the ability to pay as this will result in the highest profits. Those in poorer nations are more likely to have illness and death than those living in wealthier nations while 95\% of the people who have HIV reside in developing nations.\textsuperscript{41} Moreover, according to the United Nations Joint Programme on AIDS, lack of access to treatment has resulted in decreased survival

\textsuperscript{39} Crook at 533.
\textsuperscript{40} Madhavi Sunder, From Goods to a Good Life at 29, 2012.
\textsuperscript{41} Zita Lazzarini, Making Access to Pharmaceuticals a Reality: Legal Options Under TRIPS and the Case of Brazil at 105-106.
rates across poorer nations.\textsuperscript{42} Additionally, the inflated drug prices have caused poor nations to be unable to afford treatment and drugs due to their significant mark up. Statistics have shown that only 4.3\% of research and development for health was geared to the needs of poorer nations.\textsuperscript{43} Hopkins notes that:

"While developing countries form 80 percent of the market, new research is predominantly spent on rich country concerns...Tuberculosis, malaria, pneumonia and diarrhea account for 20 percent of world disease and are rampant in underdeveloped regions of the world but obtained less than 1 percent of the funds allocated to health research in 2002...Developed countries should recognize the role they have in ensuring that all individuals can exercise the right to public health no matter their geographical or economic location. Signatories to the UDHR declaration have an obligation to protect those beyond their own border. A global movement to shift the R&D focus beyond the bottom line figures is necessary so as to incorporate neglected developing world diseases."\textsuperscript{44}

Lazzarini notes that although high prices prevent poorer nations from access to medications and other treatment, there are also numerous other barriers.\textsuperscript{45} For instance, she explains that the lack of public infrastructure is yet another barrier as there is a lack of testing, counseling and overlooking of diseases.\textsuperscript{46} She further notes that developing nations lack clinicians and facilities who have the training and education necessary to give anti-retroviral treatment and check on the progress of the patients.\textsuperscript{47} An improved infrastructure will allow for

\textsuperscript{42} Lazzarini at 106.
\textsuperscript{44} Hopkins at 101.
\textsuperscript{45} Lazzarini at 114.
\textsuperscript{46} Lazzarini at 114.
\textsuperscript{47} Lazzarini at 114.
more doctors and better clinicians and facilities providing access and treatment so that humans infected with HIV/AIDS have the opportunity to flourish.

Although there have been numerous developments and much progress with drug inventions, the needs of the poorer nations have often been overlooked while the focus has been on wealthier nations. This poses significant issues as the majority of poverty and illnesses lie in the nations were pharmaceutical companies failed to aim their focus. For instance, Fisher and Syed state in an article entitled, “Global Justice in Healthcare: Developing Drugs for the Developing World” that “pharmaceutical firms concentrate their research and development resources on diseases prevalent in Europe, the United States, and Japan – areas from which they receive 90-95% of their revenues – and most of the diseases that afflict developing countries are uncommon in those regions.”

Statistics have shown that “neglected diseases account for 16.4% of the global disease burden. Yet, the portion of global R & D expenditures that is comprised of research directed at those diseases is in the range of 2-3%. Only 1.5% of the total global burden takes place in the developed world, where the pharmaceutical firms earn roughly 95% of their revenue.” Fisher and Syed have suggested that the amount of money spent on R&D should be increased in the areas of medications and treatments for neglected diseases by using more resources or by using some of the funds that are now being used on non-neglected diseases.

This value based approach will allow for human beings globally to live healthier lives in order to live to their best capabilities.

III. POVERTY AND ITS CONCERN

A. STOPPING THE SPREAD OF DISEASE

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49 Fisher and Syed at 612.
50 Fisher and Syed at 612-613.
Many of the diseases that affect poorer nations are excruciating both to those infected and the family members where it is accepted that the likelihood of treatment and medication is slim as these humans lack opportunity and well-being. However, these diseases also impact others who may come into contact with infected individuals. In the article “Global Health Governance” the authors state that “Globalization has introduced or intensified national borders in their origin or impact. Such risks may include emerging and reemerging infectious diseases, various noncommunicable diseases (e.g. lung cancer, obesity, hypertension).”\(^5\) It is critical to note how quickly illnesses spread impacting the entire community. Crook states that greater access to medicine will allow for political, social and economic structures to be more stable in poor nations and there should be focus on prevention and treatment of diseases.\(^5\) Fisher and Syed state that there are negative externalities with these diseases that stretch beyond the infected individuals since those around them have a higher chance of getting the illness as well as outbreaks need supra-national cooperative action.\(^5\) Thus, we should strive for the full development of humanity.

B. INCREASED TRADE AND MORE TRADING PARTNERS

Shifting the focus of pharmaceutical companies on the needs of poorer nations will not only improve health and prevent the spread of disease yet it will also help promote economic development by increased trade and allowing for a rise in the number of trading partners due to an improvement in human flourishing. Fisher and Syed have explained that trade will help both the North and the South as there will be more markets and more productivity with trading

\(^5\) Crook at 538.
\(^5\) Fisher & Syed at 588-589.
partners as there are great links between increased health of a nation and its development which will also decrease chances of instability.\textsuperscript{54}

As diseases spread, the life expectancies in poorer countries that are significantly impacted by these diseases will likely decline. This decline in life expectancies will certainly affect labor and the ability to produce and trade goods. However, allowing poorer nations to have access to medication and life-saving treatments while save lives allowing countries and its citizens to be more productive being able to work and produce goods, and this will maximize flourishing for citizens of rich countries as well.

C. THE RIGHT TO LIFE

There is a right to life which includes a right to medication in international law as well as in the South African Constitution and is consistent with a virtue ethics approach in promoting maximum human flourishing globally. Although international law documents and treaties do not specifically state that there is a right to pharmaceuticals, this right is founded in “the implications of existing substantive provisions and in the special needs created by the current circumstances.”\textsuperscript{55} For instance, the Universal Declaration of Human Rights states that there is a “right to life, liberty and security of person...[and] no one shall arbitrarily be deprived of his life.”\textsuperscript{56} The Universal Declaration of Human Rights also establishes “the right to a standard of living adequate for health and well-being of himself and his family [which] includes medical care and necessary social services, and the right to security in...sickness, disability, widowhood, old age or other lack of livelihood in circumstance beyond his control” as the UDHR has been considered customary international law.\textsuperscript{57} The International Covenant on Economic, Social, and

\textsuperscript{54} Fisher and Syed at 589-590.
\textsuperscript{55} Lazzarini at 117.
\textsuperscript{56} Universal Declaration of Human Rights, art. 3.
\textsuperscript{57} Universal Declaration of Human Rights, pmbl. 1948.
Cultural Rights (ICESCR) states in Article 12 that there is a right to “the highest attainable standard of physical and mental health” requiring states to ensure for “the provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child, the improvement of all aspects of environmental and industrial hygiene, the prevention, treatment and control of epidemic, endemic occupational and other disease [and] the creation of conditions which would assure to all medical service and medical attention in the event of sickness.”

Continually, the ICESCR creates the right to “enjoy the benefits of scientific progress.” Moreover, the WTO requires the right of “enjoyment of the highest attainable standard of health” which is considered to be a “fundamental right of every human being without distinction of race, religion, political belief, economic or social condition.”

Crook states that the Committee on Economic, Social, and Cultural Rights discusses the right to health in Article 15 which “recognizes the right of everyone to enjoy the benefits of scientific progress and its applications and to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author” “which could include access to break-through medications.” Moreover, under the International Covenant on Civil and Political Rights (ICCPR), Article 6(1) states that “Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life.” This provision can be interpreted as the right to life consisting of access to medication to allow for cure and prevent death from an illness that can be cured through prescriptions. Another example of international law which requires a right to medication

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59 Id., art. 15 § 1, ¶ b.
61 Crook at 535.
62 International Covenant on Civil and Political Rights Art. 6(1), March 23, 1976.
includes the Convention on Rights of the Child which states in Article 6 that “State parties recognize that every child has the inherent right to life. States parties shall ensure to the maximum extent possible the survival and development of the child.” The aforementioned treaties and customary international law express the right to life which is often at risk as a result of intellectual property protection. As explained by Audrey Chapman, the human rights approach focuses on protecting human dignity while balancing inventors interests which are conditioned on assisting society’s welfare.

In addition to the right to life as expressed in international law (treaties and customary international law), this right is also evident in domestic law such as in national constitutions. For instance, our very own U.S. Constitution provides in the 14th Amendment that “nor shall any state deprive any person of life, liberty, or property.” Moreover, in the South African Constitution, Article 11 provides that “Everyone has the right to life.” The South African Constitution requires the government to take reasonable measures to allow for the right to access health care services. The existence and application of a right to life is an example of a virtue ethics approach which exists and works. The right to life encompassed in the constitutions of various domestic nations demonstrates the right to access to pharmaceuticals in order to allow a person to be treated and continue to live as individuals should be allowed to live well.

IV. RECOMMENDATIONS TO BETTER BALANCE PUBLIC HEALTH AND INTELLECTUAL PROPERTY RIGHTS

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64 Audrey R. Chapman, Approaching Intellectual Property as a Human Right: Obligations Related to Article 15 (1) (c) at note 61.
65 U.S. Const. Art. XIV.
66 South Africa Const. Art. XI.
There have been some successful efforts to reduce poverty by permitting access to medication which has focused on maximizing well-being. Cantrell points out that in South Africa, Bristol-Meyers "agreed not to enforce a patent on an important AIDS/HIV medication, permitting the South African government to purchase a lower-priced generic version." The Millennium Development Goals were established to decrease poverty as part of the Millennium Declaration. The Millennium Declaration was signed in September 2000 by 189 countries.

One of the United Nations Millennium Development Goals was to halve the people whose income was under $1.25 a day in the years 1990 and 2015. The goal of halving the poverty rates was met five years before the 2015 deadline. In 2010, 700 million fewer people lived in conditions of extreme poverty compared to in 1990.

Unfortunately, 1.2 billion people still live in poverty on a global scale and we must strive for the full development of humanity. Another United Nations Millennium Development Goal was to cut the proportion of people who are undernourished by half by 2015. Across the world, approximately 870 million people are malnourished while over 100 million children below five years old are malnourished and underweight. Krishnan states that "Millennium Development Goals relating to HIV, tuberculosis and malaria, there were to have halted by 2015 and began to reverse" and "according to the 2013 report, HIV remains the leading cause of death for women of reproductive age globally with one woman dying every minute."

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68 Cantrell, at 437.
69 Vidya Krishnan, Countries meet poverty reduction goal, but trip on maternal health, July 4, 2013 at 1.
70 Krishnan at 1.
74 United Nations Millennium Development Goals at 1.
75 United Nations Millennium Development Goals at 1.
76 United Nations Millennium Development Goals at 1.
77 Krishnan at 2.
The purpose of TRIPS is “reducing distortions and impediments to international trade and ensuring that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.” However, intellectual property rights have become barriers to trade especially in relation to poorer countries receiving access to medications and treatments. Although the first line ARVs have declined in price from $10,000 per patient to $60 per patient there are only 4% of people with second line ARV medications as 14% are needed and the cost is 2.5 more expensive than the first ARV medications while the third line of ARV drugs are lacking. The prices for the ARV medications are up to 35 times the amount of nations who have greater generic competition. This lack of access hinders the achievement of maximum human flourishing and there should be a focus on humans achieving their highest potential.

Patent protection needs to be relaxed which will permit generic medications through compulsory licenses and make treatment affordable to poorer nations which would allow for an increase in human flourishing. At the same time, IP rights do need to be protected to the extent necessary to sustain the “human flourishing” of the pharmaceutical companies. Compulsory licensing has been defined by the WTO under TRIPS as follows: “when a government allows someone else to produce the patented product or process without the consent of the patent owner. It is one of the flexibilities on patent protection included in the TRIPS agreement.”

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78 Lazzarini at 109.
81 Crook at 533.
in January 2005. Furthermore, the WTO states that for compulsory licensing to be applicable there does not necessarily need to be an emergency as countries may determine when to grant compulsory licenses.

In clarifying numerous questions regarding compulsory licensing under TRIPS the WTO explains:

"The TRIPS Agreement does list a number of conditions for issuing compulsory licenses, in Article 31. In particular:

- Normally the person or company applying for a license has to have tried to negotiate a voluntary license with the patent holder on reasonable commercial terms. Only if that fails can a compulsory license be issued, and

- Even when a compulsory license has been issued, the patent owner has to receive payment; the TRIPS Agreement says "the right holder shall be paid adequate remuneration in the circumstances of each case, taking to account the economic value of the authorization" but it does not define "adequate remuneration" or "economic value."

It cannot be given exclusively to licensees (e.g. the patent holder can continue to produce), and it should be subject to legal review in the country."

Additionally, TRIPS states that for "national emergencies", "other circumstances of extreme urgency" or "public non-commercial use" (or "government use") or "anti-competitive practices", a voluntary license is not required as this step can be skipped when time is crucial, however; the patent owner must still be compensated. Adequate compensation is determined

83 World Trade Organization, Compulsory licensing of pharmaceuticals at 1.
84 World Trade Organization, Compulsory licensing of pharmaceuticals at 1.
85 World Trade Organization, Compulsory licensing of pharmaceuticals at 1.
86 World Trade Organization, Compulsory licensing of pharmaceuticals at 1.
by officials in the concerned country while the patent owner may appeal. The TRIPS agreement in Article 31 had previously stated that compulsory licenses were to be given for the domestic market. However, at the Doha Conference in 2001, this provision was changed to allow nations who were unable to create the pharmaceuticals to be able to get them at a lower price from somewhere else if needed. The purpose of changing this provision was to create a way to “allow generic copies made under compulsory licenses to be exported to countries that lack production capacity” which will allow for well-being.

Similarly, according to the IP unit and members of the University of KwaZulu-Natal, South Africa can specifically focus on generic medications in order to foster flourishing. Furthermore, compulsory licenses are not limited to emergencies and can be issued if there is a shortage in supply to the market, “a desire to make fixed-dose combinations of medicines owned by different right holders, dependent patent that is technologically important, desire to have multiple sources of supply to prevent shortfalls of stock, and even a desire to promote local production where there have been failures in technology transfer from right holders.” A focus on generics will allow for human good and will allow individuals to live well.

Twenty-three nations have decided that they would not use compulsory licensing in importing including: “Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and the US. Since they joined the EU, the list now includes 10 more: Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania,

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Malta, Poland, Slovak Republic and Slovenia.”

Eleven other nations have stated that they would only use compulsory licenses if there is a national emergency or “extreme urgency” including: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, and United Arab Emirates. While it is known that twenty-three nations will not use compulsory licensing for importing and eleven others agreed only to use compulsory licensing in extreme emergencies, it is evident that compulsory licenses for pharmaceuticals have received serious criticism as interfering with intellectual property rights of the inventor. The WTO stresses that all of the obstacles have not been removed as in order to use compulsory licensing, exporting countries must also modify their laws so that they are consistent with the modifications made under TRIPS rather than simply allowing compulsory licensing mainly for their domestic use. Presently, Norway, Canada, India and the EU have modified their laws to be consistent with the changes under TRIPS.

In 1965, South Africa realizing that the IP laws at the time were not conducive to flourishing, amended the Medicines Act in order to increase availability of medicines which has been an effort towards improving well-being. The nation’s office for patents is in the Companies and IP Commission which was created by the Companies Act and is responsible for registering the patents. However, patent applications are not thoroughly examined. The Court for patents is the Commissioner of Patents who has authority under the Patents Act to make rulings regarding infringements and compulsory licenses. Patents are maintained in the

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93 World Trade Organization, Compulsory licensing of pharmaceuticals at 2.
94 World Trade Organization, Compulsory licensing of pharmaceuticals at 2.
95 World Trade Organization, Compulsory licensing of pharmaceuticals at 2.
97 Park, Prabhala and Berger at 22.
98 Park, Prabhala and Berger at 22.
99 Park, Prabhala and Berger at 24.
Patent Journal that is now available electronically.\textsuperscript{100} Under the Patents Act, the process for compulsory licensing is both long and expensive and must be brought before the Commissioner in a judicial proceeding which can take three or even more years as the process has been criticized for being unclear as the application goes to the commissioner, the judge of the High Court which results in high costs due to arguments, adjournments and undue delays.\textsuperscript{101} However, TRIPS does not require the strict requirements adopted by South Africa in order to obtain a compulsory license.\textsuperscript{102} It has been suggested that specific standards should be implemented in order to help the Commissioner when deciding what is considered adequate in terms of remuneration in order to avoid long litigation and high costs.\textsuperscript{103} By allowing for more specificity in standards for compulsory licenses, generic companies will be able to better “negotiate voluntary licenses on reasonable terms”, produce more and provide greater access.\textsuperscript{104} For instance, Canada caps the royalty rate to be 4% of the generic product’s price.\textsuperscript{105} According to the United Nations Development Programme, “there may be cases in which the issuance of a compulsory license is not a sufficient remedy for certain anti-competitive practices” and in those cases patents should be able to be revoked in order to prevent abuses.\textsuperscript{106} Presently, a compulsory license for generic versions of the third line ARV is in dire need as there are no generics for the third line of treatment currently available.\textsuperscript{107}

Another suggestion is to allow parallel imports to allow for human good by wider access to medicines. Parallel imports are defined by the World Health Organization as “imports of a

\begin{thebibliography}{99}
\bibitem{100} Park, Prabhala and Berger at 24.
\bibitem{101} Park, Prabhala and Berger at 24.
\bibitem{102} Park, Prabhala and Berger at 24.
\bibitem{103} Park, Prabhala and Berger at 24.
\bibitem{104} Park, Prabhala and Berger at 62.
\bibitem{105} Park, Prabhala and Berger at 63.
\bibitem{106} Park, Prabhala and Berger at 74.
\bibitem{107} Fix the patent laws at 1.
\end{thebibliography}
patented or trademarked product from a country where it is already marketed. The World Health Organization provides examples of parallel importing and also explains the consequences that will result from parallel importing as follows:

"In Mozambique 100 units of Bayer's ciprofloxacin (500mg) costs US$740, but in India Bayer sells the same drug for US$15 (owing to local generic competition). Mozambique can import the product from India without Bayer's consent. According to the theory of exhaustion of intellectual property rights, the exclusive right of the patent holder to import the protected product is exhausted, and thus ends, when the product is first launched on the market. When a state or group of states applies this principle of exhaustion of intellectual property rights in a given territory, parallel importation is authorized to all residents in the state in question. In a state that does not recognize this principle, however, only the patent holder who has been registered has the right to import the protected product... Parallel imports often takes place when there is differential pricing of the same product - either brand-name or generic drugs - in different markets (usually owing to local manufacturing costs or market conditions)... Parallel imports can reduce the price of health products and pharmaceuticals by introducing competition. However, they can also affect the negotiation of tiered pricing regimes with pharmaceutical companies. If a private pharmaceutical company agrees to sell a product at a lower price in poor countries, it will need some assurance that the cheaper product will not be imported back into its rich country markets, undercutting its profits (product diversion)."

Hopkins writes that parallel importing "[with] generic pharmaceuticals, [has allowed] members of Kenya's non-profit sector [to] successfully lower the cost of anti-retroviral triple
therapy drugs by 40%-65%...[as parallel importing] endorses price equity in the market."110 As pointed out by the World Health Organization if parallel importing is permitted, pharmaceutical companies will be less likely to agree to tiered pricing which is another alternative. For instance, Crook suggests that there should be different pricing structures according to a formula for countries based on their per capita income, resources and the necessity for instantaneous medication.111 The strategy of pricing structures means that there would be price discrimination in that pharmaceutical companies would offer medications at lower prices in some nations while being able to keep higher prices in other nations.112 A pricing structure is not currently in place as all countries must pay the same inflated price preventing poorer nations from having access to treat diseases. For instance, Fisher and Syed have promoted changes to laws based on the distribution of pharmaceutical innovations by allowing more governmental control over the prices set for the medications while also allowing governments to oversee how pharmaceutical companies choose to invest and focus their research and development.113 For them, greater governmental control means greater access.

In South Africa, under the Minister of Health v. Treatment Action Campaign, it was ruled in 2002 that health care services consist of access to medicines.114 According to the wording of the South African Constitution, the government must adopt a legal framework to allow for access to essential medicines but also to take action in order to allow for a decline in drug prices in the private sector while making sure that there is an adequate supply of the medication which may

110 Hopkins at 92.
111 Crook at 547.
112 Lazzarini at 125.
113 Fisher and Syed at 674.
include direct price controls. Allowing for an adequate supply of medication through price controls is consistent with allowing for human good. The government can implement direct price controls by creating state guidelines for price-setting to allow manufacturers to create prices and state factors to be relevant in setting prices. Furthermore, the government can enact legislation which prohibits high prices or can set direct price controls capping prices.

Another suggestion has been to provide public funding such as government subsidies in order to help pharmaceutical companies by allowing them to have funds for continued research and development in order to continue with medication developments. By implementing the aforementioned suggestions, the concerns of proponents of intellectual property rights will be addressed since inventors will still be able to enjoy the “fruits of their labor” but would be prevented from charging extremely inflated prices. This would allow poorer nations to be able to purchase medications and treatments as pharmaceutical companies would also look to address the concerns and needs of poorer nations suffering from diseases while focusing their research and development on these concerns.

Additionally, the Department of Trade and Industry suggested on September 4, 2013 that South Africa can have national policies such as taxes on medicines to promote well-being. A further suggestion is to enact legislation to limit patents while allowing for generics in order to promote competition in order to allow for lower prices. The Department has also suggested that distribution and manufacturing capacities be improved. The Department notes that a

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118 Fisher and Syed at 674.
119 Fisher and Syed at 674.
current issue in South Africa is that the nation does not thoroughly look at patent applications and allows for companies to have numerous patents on the same medication even if they do not qualify as an “innovation” by definition which results in corporations to “extend the life of their monopolies, block competition from generic manufacturers and charge inflated prices for medicines in both the public and private sector.” Another suggestion by the Department is that a solution would be to create a more strict definition for innovation and not allow patents when current medications are combined or allowing patents for new uses of the patented drugs. In other words, South Africa should not grant patents for existing medications that have very small chemical changes. Other recommendations in at a WHO Executive Board Meeting in January 2014 in a Draft Resolution included limiting patents to only 20 years, having a more thorough examination process for patents and focusing on parallel importation and compulsory licenses. South Africa grants numerous patents as 2,442 patents were granted in 2008 alone while countries such as Brazil only granted 278 patents from 2003-2008. Furthermore, applying for patents is twenty times cheaper than the majority of patent offices as South Africa lacks a thorough patent examination process as this simplicity allows for more patents and less access to medications due to the approved patents hindering humans from achieving maximum potential by preventing individuals from living well with the ability to have medicines.

Further, the Department of Trade and Industry suggests this system could provide for specific legislation to allow a right to healthcare under the South African Constitution.
South African government has provided for the anti-retroviral treatment while also providing counseling and testing which has had success.\textsuperscript{129} South African President Zuma stated that 10 new hospitals were build or renovated and that the nation would begin “a new phase in the implementation of the National Health Insurance programme, which will extend quality healthcare to the poor...[as there will also be] construction of 300 new health facilities, including 160 new clinics” as efforts to decrease the number of people with HIV/AIDS in South Africa.\textsuperscript{130}

Another suggestion is that in order to shift the focus of pharmaceutical companies towards the needs of poorer nations, developed nations should create public-private partnerships amongst pharmaceutical companies and governments in order to promote research and development towards world diseases.\textsuperscript{131} Public-private partnerships “would be based on mechanisms of incentives where governments agree to purchase developed vaccines from firms at a pre-negotiated price upon development, focusing on medicines in developing countries such as malaria vaccines.”\textsuperscript{132}

The eighth Millennium Development Goal was to create a global partnership for development.\textsuperscript{133} The World Health Organization stated the goal was to work with pharmaceutical companies to allow for access to “affordable essential medicines in developing countries.”\textsuperscript{134} The WHO reported that:

“Although nearly all countries publish an essential medicines list, the availability of medicines at public-health facilities is often poor. Surveys conducted in over 50 low- and middle-income

\textsuperscript{129} DTI’s draft IP policy lays foundation to prevent abusive patenting at 1, 2013.
\textsuperscript{130} SA to expand HIV treatment programme at 1.
\textsuperscript{131} Hopkins at 101.
\textsuperscript{132} Hopkins at 101.
\textsuperscript{133} World Health Organization, MDG 8: develop a global partnership for development at 1, April 2013, http://www.who.int/topics/millennium_development_goals/medicines/en/index.html.
\textsuperscript{134} World Health Organization, MDG 8: develop a global partnership for development at 1.
countries indicate that the availability of selected generic medicines at health facilities was only 38% in the public sector and 64% in the private sector. Lack of medicines in the public sector forces patients to purchase medicines privately. In the private sector, generic medicines cost on average six times more than their international reference price, while originator brands are generally even more expensive. High prices often make medicines unaffordable, with common treatments costing the lowest paid government worker several days' wages.”

Furthermore, the WHO’s approach in creating a global partnership for access to essential medications includes certain activities such as:

- “WHO has developed global indicators for availability, price and affordability of essential medicines.
- WHO/Health Action International pricing survey methodology used in over 50 countries has increased awareness of the pricing, affordability and availability of branded and generic medicines in the public and private sectors.
- WHO provides pharmaceutical manufacturers with the information they need to produce quality, safe, effective essential medicines to address leading public health concerns.
- WHO offers essential capacity building and quality assurance monitoring for over 250 medicines to treat millions of patients with HIV/AIDS, tuberculosis and malaria, and with reproductive health needs in developing countries.”

Additionally, it is important that state and non-state actors are both involved in order to achieve global justice with access to medication and treatment. According to Dodgson, Lee and Drager, “liberal-internationalist scholars view the purpose of global governance as ultimately moving towards a more liberal democratic global order in which states and IGOs have equal roles. Within such an order it is envisaged that power and influence will flow in a top-down manner.” Continually, cosmopolitan democrats are proponents of diverse people within a

135 World Health Organization, MDG 8: develop a global partnership for development at 1.
136 World Health Organization, MDG 8: develop a global partnership for development at 1.
137 Dodgson, Lee and Drager, at 16.
138 Dodgson, Lee and Drager, at 16.
collaborative political community including IGOs and a larger international legal system. Despite the numerous approaches to global governance, there is a need for a global framework as suggested by Dodgson, Lee and Drager it is essential to establish leadership and authority with health governance globally as there must be sufficient resources “for health cooperation” as the resources must be “distributed appropriately according to agreed priorities.” These priorities should be based upon the principle maximization of human flourishing.

V. CONCLUSION

Pharmaceutical companies have a tremendous impact on the global access to medicine. Oftentimes, the focus of pharmaceutical companies is on the wants of the richer nations in order to increase their profits. However, this has led to lack of access to medication in poorer nations where humans have suffered and died as a result of lack of access to medications and treatments. Pharmaceutical companies, governments and international trade organizations have largely maintained policies regarding IP rights which are based upon utilitarian economics. In other words, they have promoted and sustained policies which purport to provide the greatest good to the greatest number of people. The evidence outlined above shows that these policies do not work this way. Indeed, in order to fulfill the utilitarian goal it must be scraped. The more effective approach as outlined above is a virtue ethics one with a focus on striving for the full development of humanity in order to allow for a human good. An example of this is the right to life law which has been provided for in many international law treaties as well as international customary law. This right includes the right to access to medications which will allow individuals to live well. Some suggestions for allowing access to medication to poorer nations in dire need of these treatments include compulsory licenses, public funding as well as a tiered-

139 Dodgson, Lee and Drager, at 16.
140 Dodgson, Lee and Drager, at 20-22.
pricing system which would make medications accessible to poorer nations while still providing for intellectual property protection and revenues for pharmaceutical companies. Access to medication to poorer nations will help prevent the spread of diseases in those nations and across the globe and will at the same time be beneficially to the economy in that poorer nations will be able to trade with other nations allowing for more products and trading partners. Pharmaceutical companies should focus their resources and research and development more towards these poorer nations in order to reduce illnesses in those nations as ethics require which will allow for humans achieving their maximum potential.\textsuperscript{141}

\textsuperscript{141} Dodgson, Lee and Drager, at 20-22.