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The Past, Present, and Future of South Africa's Patent System

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I. INTRODUCTION

This note looks to the history of the Republic of South Africa's (South Africa) patent law system, ¹ the present state of South Africa's patent system, and the effect its patent system has had on the country. ² The goal of this note is to develop a strategy for South Africa's patent system that better serves its country's socioeconomic situation. ³

II. HISTORICAL DEVELOPMENT OF SOUTH AFRICA'S PATENT SYSTEM

A. Brief History of Colonial South Africa

In the mid-seventeenth century, settlers from the Netherlands colonized the Western Cape of South Africa.⁴ In 1806, the British defeated the Dutch settlers and claimed the Cape for the British Empire.⁵ The current laws of South Africa reflect this successive colonial governance.⁶ "The 'common law' of the country (in this context, 'common law' implies law of non-statutory origin) is based on the 'Roman-Dutch' law of the original Dutch settlers."⁷

When the British Empire took the Cape of South Africa in 1806, they did not impose their legal system, at least not completely. Instead, the existing Roman-Dutch common-law remained in force, but was eventually "overlaid with a heavy English law influence." The English influence included enacting English procedural law, basing statutory acts on English acts, and interpreting statutes with relevant English precedent. Advocates and judges of the courts were usually trained in England as well. 11

Nearly one hundred years later, after the South African Anglo-Boer War that

¹ See infra Part II.

² See infra Part III.

³ See infra Part IV.

⁴ Amanda Barratt & Pamela Snyman, *Researching South African Law*, GLOBALEX (Mar. 2005), http://www.nyulawglobal.org/Globalex/South_Africa.htm.

⁵ See MICHAEL MORRIS, EVERY STEP OF THE WAY: THE JOURNEY TO FREEDOM IN SOUTH AFRICA 72 (John Linnegar ed., 2004) ("[B]efore Britain returned at the second occupation in 1806 for an extended and decisively influential stay - the Cape was regarded as being what Penn has described as 'a British Responsibility'."); Barratt & Snyman, *supra* note 4.

⁶ Barratt & Snyman, *supra* note 4.

⁷ *Id.* Many of the primary sources of South African law stemmed from Roman law as interpreted by Dutch writers. *Id.*

⁸ *Id*.

⁹ *Id*.

¹⁰ *Id*.

¹¹ *Id*.

ended in 1902, Britain took control of the entirety of South Africa. ¹² In 1910, Britain unified the four territories of South Africa. ¹³ During the unification process, the legal systems of the territories were made more consistent with that of the Cape. ¹⁴

The resulting South African legal system is regarded as a true hybrid of both English law and Roman-Dutch legal principles. However, South Africa's laws do not completely ignore native heritage. A "Native Administration" policy developed during English governance allowed indigenous people to "rule themselves according to indigenous law in certain matters." This plural legal system exists today with the limitation that the Native Administration rulings may not preempt the South African Constitution. 18

When the National Party took control of the government in 1948, the long existing segregationist policies of apartheid became the official South African government policy. During Apartheid, the population was classified in racial groups and geographically segregated; the extent of the segregation included nearly every aspect of life: education, health services, employment, and public amenities. Many South Africans lost their citizenship and were forced into separate states outside of 'white South Africa. As resistance to the apartheid regime grew, the South African government implemented laws giving the state powers to detain, arrest, imprison, and ban its opponents.

In 1990, the government began negotiations with its opponents, which resulted in the Interim Constitution.²³ In 1994, democratic elections led to Nelson

¹² Jim Jones, *South Africa in the 19th Century*, W. CHESTER U., http://courses.wcupa.edu/jones/his312/lectures/southafr.htm (last visited Apr. 19, 2012); Barratt & Snyman, *supra* note 4

¹³ Barratt & Snyman, *supra* note 4. The four South African territories unified were: the Cape, Natal, the Orange Free State, and the Transvaal. *Id*.

^{&#}x27; Id.

¹⁵ *Id*.

¹⁶ Barratt & Snyman, *supra* note 4.

¹⁷ *Id.* "The colonial state retained exclusive jurisdiction over matters such as serious crime. Matters of customary law were heard by chiefs and headmen, with a right of appeal to the Native Appeal Court, staffed by magistrates." *Id.*

¹⁸ *Id*.

¹⁹ *Id*.

 $^{^{20}}$ Laurel Baldwin-Ragaven et al., An Ambulance of the Wrong Colour: Health Professionals, Human Rights and Ethics in South Africa 18–19 (1999); Barratt & Snyman, $\it supra$ note 4.

²¹ Barratt & Snyman, *supra* note 4.

 $^{^{22}}$ Id

²³ S. Afr. (Interim) Const., 1993; *South Africa: The Presidency of Nelson Mandela* (1994-1999), Electoral Inst. for the Sustainability of Democracy in Afr..

Mandela's election as President.²⁴ Three years later, a final constitution was enacted into law with a Bill of Rights.²⁵

The Republic of South Africa's relation to Europe through colonization and adoption of their legal and political structures is an important backdrop that helps to explain South Africa's international intellectual property policy. A policy that for the last two decades has arguably strayed away from what is in the country's best interests.

B. Balancing Justifications for and Against a Patent System

In industrialized nations, such as the United States, the pro-patent sentiment outweighs any human rights argument against patent protection. The economic prosperity in industrial nations makes them ideal candidates for a patent system, as the population is capable of absorbing the economic costs of more costly goods due to patent-based monopolies. The net gain for these industrialized nations is an improved standard of living.

However, in third-world-developing countries, such as South Africa, is adopting an international patent system truly advantageous to the nation's economy, or is South Africa playing with the "big boys" at a detriment to their country's well-being? It is the view of this author, based on the analysis to follow, that South Africa has entered the international intellectual property rights arena at its own detriment.²⁶ Particularly important to this analysis of South Africa's patent system is a discussion of factors that make South Africa unique among fellow third-world countries entering the international patent arena, including the HIV/AIDS epidemic and extreme poverty.²⁷

1. Policy Justifications for a Patent System

There are essentially two broad justifications for patenting. One is based on the natural right of the inventor (fundamental justice), and the other justification is based on a discretionary act of the sovereign (economic justice).²⁸

Under the natural right of fundamental justice, "justice inherently requires society to transfer to the inventor the right of control." This is due to an

http://www.eisa.org.za/WEP/souoverview8.htm (last updated Feb. 2011); Barratt & Snyman, *supra* note 4.

²⁴ Barratt & Snyman, *supra* note 4.

²⁵ S. AFR. CONST., 1996; Barratt & Snyman, *supra* note 4.

²⁶ See infra Parts III–IV.

²⁷ See infra Part II.B.3.

²⁸ 1 R. Carl Moy, Moy's Walker on Patents § 1:26 (4th ed. 2010) (citations omitted).

inventor's inherent property right in their invention.³⁰ The fundamental justice view is supported by Lockean theory that individuals own themselves, and by extension, the fruits of their labor.³¹ The association of labor and an item created by that labor thus creates a property interest in the creator.³² It follows that inventors should be granted a right to exclude others from the use of their invention via a patent system.

Under the economic justification, the sovereign is acting on behalf of the public: "patent rights are given when the patenting transaction is one from which the public expects to benefit. Where it seems that the public would suffer net losses, in contrast, the patent is denied." The patent system under this justification is looked at as a tool to increase society's welfare. Most often, this societal welfare is viewed in economic terms, the goal being to maximize society's aggregate wealth. The patent system under this patent is viewed in economic terms, the goal being to maximize society's aggregate wealth.

"Dating back to ancient Greece, one can discern at least the idea of an incentive-based mechanism wherein a potential inventor is encouraged to disclose something new and useful to society. The incentive could take the form of a prize reward or exclusive right in the inventor's contribution." The patent grant is intended to incentivize and "promote the progress of science and useful arts." This incentive spurs innovation, with the innovation ultimately benefitting the society that grants the patent.

2. Policy Justifications Against a Patent System

"The grant of patent rights is thought to impose a wide array of costs on society." The most apparent cost is operating a government-run patent system. In the United States, "the Federal Government incurs significant expenses to operate the patent-related portions of the Patent and Trademark Office." A patent system also requires considerable resources from the legislative and

³⁰ Karen Vaughn, *John Locke and the Labor Theory of Value*, 2 J. LIBERTARIAN STUD. 311 (1978), *available at* http://mises.org/journals/jls/2_4/2_4_3.pdf; *see generally* 1 MOY, *supra* note 28, § 1:28.

³¹ Joan E. Schaffner, *Patent Preemption Unlocked*, 1995 WIS. L. REV. 1081, 1089–92 (1995); 1 MOY, *supra* note 28, § 1:28.

³² 1 Moy, *supra* note 28, § 1:28.

³³ *Id.* § 1:26.

³⁴ *Id.* § 1:29.

 $^{^{35}}$ Id

³⁶ F. SCOTT KIEFF ET AL., PRINCIPLES OF PATENT LAW 6 (4th ed. 2008).

³⁷ U.S. CONST. art. I, § 8, cl. 8.

³⁸ 1 Moy, *supra* note 28, § 1:30.

³⁹ *Id*.

⁴⁰ *Id*.

judicial branches.⁴¹ Patent-owning interests incur costs in using the system, including obtaining and retaining patents, licensing, and enforcing their patent rights.⁴² Accused infringers incur costs in defending themselves.⁴³ The net result of these social costs is increased costs to the consumer, in the form of higher taxes and increased cost of consumer goods.

Typically, goods in an open market are controlled by a standard supply and demand curve, which dictates price.⁴⁴ If only a single source for a good exists, other sources will enter the market if the original source is artificially altering the supply and demand curve to induce a higher price and profit margin.⁴⁵ A fully competitive market will self-correct until all suppliers' selling prices of a particular good represents the goods' cost of production, plus a normal rate of return.⁴⁶

When patent rights control goods, the above situation no longer applies.⁴⁷ The patent owner in this case, by excluding others from supplying the goods to the market, may manipulate the supply that the market receives, maximizing profit.⁴⁸ This market manipulation is not corrected by the influx in additional suppliers as is seen in a fully competitive market.⁴⁹ The patent owner controls all entrance into the market for their patent protected good until the end of their exclusivity period.⁵⁰ The marketplace change that results from patent protection gives rise to two primary consequences.⁵¹

The increase in price for the patent protected good results in a large transfer of wealth to the patent owner from consumers, exacerbating inequalities in the distribution of wealth.⁵² This wealth transfer can be even more harming to a

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 $^{^{41}}$ Id

⁴² Gene Quinn, *The Cost of Obtaining a Patent in the US*, IPWATCHDOG (Jan. 28, 2011, 1:14 PM), http://www.ipwatchdog.com/2011/01/28/the-cost-of-obtaining-patent/id=14668/ (providing a modern example of all the costs associated with obtaining a United States Patent); 1 MOY, *supra* note 28, § 1:30.

⁴³ Moy, *supra* note 28, § 1:30.

⁴⁴ See generally Making World Development Work: Scientific Alternatives To Neoclassical Economic Theory (Grégoire LeClerc & Charles A.S. Hall eds., 2007).

⁴⁵ *Id*.

⁴⁶ *Id*.

⁴⁷ 1 Moy, *supra* note 28, § 1:31.

⁴⁸ See generally Paul E. Schaafsma, An Economic Overview of Patents, 79 J. PAT. & TRADEMARK OFF. SOC'Y 241 (1997); 1 Moy, supra note 28, § 1:31.

⁴⁹ See 1 Moy, supra note 28, § 1:31; Schaafsma, supra note 48 at 248–49.

⁵⁰ See 1 Moy, supra note 28, § 1:31; Schaafsma, supra note 48 at 248–49.

⁵¹ See 1 Moy, supra note 28, § 1:31.

⁵² *Id*.

country's economy when it benefits a foreign entity, "a prime motivation for some countries to deny or restrict the grant of patent rights to foreigners." ⁵³

As discussed above, the patent owner maximizes profit by manipulating the supply of the patented product that the market receives, the manipulation typically being a decreased supply of the goods.⁵⁴ A fully competitive market represents the optimal rate at which the goods can be used by society; when patents protect a good, society's use of the good becomes too low.⁵⁵ Also, the patent acts as a barrier to entry for entities to which the advance is useful; this retards the growth of the entities within the industry the patent is useful.⁵⁶ These factors combine to create the problem of social underutilization in which a society pays a heavy burden for a limited benefit.⁵⁷

One element of the heavy burden society pays is through the allocation of the undersupply of the patented good.⁵⁸ The limited supplies of goods are sold to those who are willing to pay the most.⁵⁹ Therefore, "that system will allocate the decreased supply of the patented goods to the wealthiest portions of society, and impose the under supply on the portion that is least wealthy."⁶⁰ In the case where the goods are not fundamentally important to life, this effect of a patent system has little opposition.⁶¹ However, when the invention is fundamental, such as pharmaceuticals or life-sustaining goods, it is highly debated whether this is an acceptable casualty of a patent system.⁶² In this analysis of South Africa's patent system, access to essential medicines for HIV/AIDS is of particular importance in determining whether South Africa's patent system is detrimental to the health and welfare of its people.

- 3. Human Rights Concerns
- a. HIV/AIDS & Access to Essential Medicines

One of the strongest arguments against a patent system is evident when that system disregards the most fundamental human right, the right to life. In South

⁵³ *Id*.

⁵⁴ See generally 1 Moy, supra note 28, §§ 1:31, 1:32; Schaafsma, supra note 48 at 246–47.

⁵⁵ See generally Corinne Langinier & GianCarlo Moschini, *The Economics of Patents: An Overview* 3–5 (Iowa St. Univ. Ctr. for Agric. & Rural Dev., Working Paper No. 02-WP 293, 2002), *available at* http://www2.econ.iastate.edu/research/webpapers/paper_2061.pdf; 1 MOY, *supra* note 28, § 1:32.

⁵⁶ 1 Moy, supra note 28, § 1:32; see generally Langinier & Moschini, supra note 55, at 3–5.

⁵⁷ 1 Moy, *supra* note 28, § 1:32; *see generally* Langinier & Moschini, *supra* note 55, at 3–5.

⁵⁸ 1 Moy, *supra* note 28, § 1:32; *see generally* Langinier & Moschini, *supra* note 55, at 3–5.

⁵⁹ 1 Moy, *supra* note 28, § 1:32.

⁶⁰ *Id*.

⁶¹ *Id*.

⁶² *Id*.

Africa's developing third-world economy, the country's need for a patent system that promotes innovation is evident, but must be balanced with the population's need for basic necessities.

South Africa, for the past several decades, has been plagued with an HIV epidemic that now claims nearly 200,000 lives a year. Nearly "5.6 million South Africans were living with HIV at the end of 2009, including 300,000 children under 15 years old." HIV prevalence is nearly 18% among 15-49 year olds, and the epidemic is almost completely isolated to the African demographic. South African demographic.

Fighting the HIV/AIDS epidemic has been greatly hindered by the cost of AIDS medications, including antiretroviral treatments. In 1996, brand name antiretroviral drugs, costing over USD \$10,000 per person per year, were far too expensive for the majority of people infected with HIV in lower- and middle-income countries.⁶⁶

However, great strides have been made in reducing the cost of medication. Under the TRIPs⁶⁷ agreement, developing signatory countries were allowed a transition periods in which to comply with pharmaceutical industries' rights.⁶⁸ This allowed developing countries, such as India, to continue to develop generic drugs until 2005.⁶⁹ These generic drug companies sparked a price war, causing branded drug makers to reduce the price of antiretroviral for developing countries throughout the mid-2000s.⁷⁰ As a result of country-dependent tiered pricing and international negotiations with branded pharmaceutical companies, the cost of antiretroviral treatments in 2011 is down to USD \$159 per person per year.⁷¹ Though a great improvement in price, "[t]he per capita income of a black person

⁶³ South Africa HIV & AIDS Statistics, AVERT, http://www.avert.org/safricastats.htm (last visited Apr. 19, 2012) ("A computer model made by the Actuarial Society of South Africa, called ASSA2008 calculated that the number of people who died of AIDS declined from an estimated 257,000 in 2005 to 194,000 in 2010." citing ASSA AIDS Model 2008 Media Release, ACTUARIAL SOC'Y OF S. AFR. (Mar. 9, 2011), available at http://aids.actuarialsociety.org.za/News-3139.htm).

⁶⁴ *Id.* (citing *UNAIDS Report on the Global AIDS Epidemic*, UNAIDS (2010), available at http://www.unaids.org/globalreport/).

⁶⁵ *Id.* ("UNAIDS estimated that HIV prevalence was 17.8% among 15-49 year olds at the end of 2009.").

⁶⁶ Reducing the Price of HIV/AIDS Treatment, AVERT, http://www.avert.org/generic.htm (last visited Apr. 19, 2012) (citations omitted).

⁶⁷ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 (1994) [hereinafter TRIPs].

⁶⁸ Reducing the Price of HIV/AIDS Treatment, supra note 66.

⁶⁹ *Id*.

⁷⁰ *Id*.

⁷¹ *Id*.

in South Africa is USD \$271."⁷² Living below the poverty line, it is unreasonable to believe that they can afford a treatment that is more than half-a-year's wages when they are unable to afford basic necessities.

The costs of medication combined with extreme poverty are major factors in both the spread and mortality rate of HIV/AIDS in South Africa.

b. Extreme Poverty

Nearly 60% of individuals in South Africa are living below the poverty income line, encompassing 25 million people. [T]he poverty gap has grown faster than the economy indicating that poor households have not shared in the benefits of economic growth."

South Africa's HIV/AIDS epidemic and extreme poverty are of great concern both to the country and to the world as a whole. Both of these aspects of South Africa's socioeconomic situation must be considered as both effects of South Africa's patent system⁷⁵ and as a driving force in developing South Africa's patent system to better serve their country.⁷⁶

C. Regional Patent Systems in Africa

South Africa has yet to join one of the two regional patent systems in Africa, however, there has been speculation for a number of years that South Africa will join ARIPO.⁷⁷ The following section briefly discusses the two regional patent systems in Africa, the African Regional Intellectual Property Organization (ARIPO) and the African Intellectual Property Organization (OAPI).⁷⁸ Both ARIPO and OAPI reflect the allegiance of African countries to the colonial legal systems of English common law and French continental law.⁷⁹ Both

⁷² *Cartilha*, REDE SOCIAL, http://www.social.org.br/cartilhas/cartilhaingles003/cartilha009.htm (last visited Apr. 19, 2012).

⁷³ Craig Schwabe, *Fact Sheet: Poverty in South Africa*, S. AFR. REGIONAL POVERTY NETWORK (July 26, 2004), http://www.sarpn.org/documents/d0000990/ ("While the poverty rate measures the proportion of a region's population living below the poverty line it does not give any indication of how far below the poverty line poor households are.").

⁷⁴ See id. ("[T]he poverty gap . . . measures the required annual income transfer to all poor households to bring them out of poverty.").

⁷⁵ See infra Part III.

⁷⁶ See infra Part IV.

⁷⁷ Peter James, *Regional Patent Systems in Africa*, FED'N. INTÉRNATIONALÉ DES CONSEILS EN PROPRIÉTÉ INDUSTRIELLE (Nov. 3, 1999),

http://www.ficpi.org/library/montecarlo99/patentsafrica.html.

⁷⁸ Adebambo Adewopo, *The Global Intellectual Property System and Sub-Saharan Africa: A Prognostic Reflection*, 33 U. Tol. L. Rev. 749, 765 (2002).

organizations, ARIPO and OAPI, are examples of how South Africa could adapt their patent system to better reflect the needs of their country and the economic and social needs of the region.

1. OAPI

The African Intellectual Property Organization was established by French-speaking Africa, in collaboration with France's National Institute of Industrial Property for registration and grant of industrial property rights. It was signed as an Agreement Relating to the Creation of an African Intellectual Property Organization on March 2, 1977 at Bangui. The laws, modeled after the French laws of 1844, 1857, and 1909, were originally established under the 1962 Libreville Agreement (then known as the African and Malagasy Office of Industrial Property). The revised text was signed in 1977 and only took effect in February 1982.⁸⁰

The membership of OAPI includes: Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Djibouti, Gabon, Guinea, Ivory Coast, Mali, Mauritania, Niger, Senegal, Togo, and Guinea-Bissau. Members of the OAPI agreement also consent to two international conventions, the Patent Cooperation Treaty of 1970 (PCT) and the Trademark Registration Treaty of 1973. ⁸²

The agreement puts in place common administrative procedures through centralization of applications and registration of all forms of intellectual property. The agreement puts in place a uniform system of laws applicable to all member states covering: patents, utility models, trademarks and service marks, copyrights, and cultural heritage. The agreement puts in place a uniform system of laws applicable to all member states covering: patents, utility models, trademarks and service marks, copyrights, and cultural heritage.

Although OAPI has accepted the PCT, they have adapted their patent system to better serve their region. The PCT's high requirement for patentability has been relaxed in the OAPI to better accommodate the low technological skill levels of member states. The OAPI agreement allows for deferred examination as to substance for ten years, then providing for an additional five years of deferment for the inventor to prove working of the patent in one of the member states. The objective states are to be the patent in one of the member states.

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⁸⁰ *Id.* at 767 (footnote omitted).

⁸¹ James, *supra* note 77.

⁸² Adewopo, *supra* note 78, at 767 (citations omitted).

 $^{^{83}}$ Id

⁸⁴ Id.; see also James, supra note 77.

⁸⁵ See Adewopo, supra note 78, at 767; James, supra note 77 (discussing the OAPI's use of its own Search report rather than the report generated by a PCT Search Report).

⁸⁶ Adewopo, *supra* note 78, at 767–68 (footnote omitted).

⁸⁷ *Id.* at 767.

Also, the OAPI agreement allows inventors to file certificates for changes, improvements, or additions over the principal patent. 88

2. ARIPO

The ARIPO, when first created on December 9, 1976, was known as the Industrial Property Organization for English-speaking Africa. ARIPO's objectives include studying, promoting, and cooperating "on matters relating to industrial property in collaboration with the Economic Commission for Africa, WIPO, and Organization for African Utility." ⁹⁰

The objectives of the organization include: (a) promotion of the harmonization and development of industrial property laws and matters related thereto, appropriate to the needs of its members and of the region as a whole; (b) establishment of such common services or organs of harmonization and development of the industrial property activities affecting its members; (c) assisting its members in the development and acquisition of suitable technology; and, (d) evolution of a common view in industrial property matters.⁹¹

The membership of ARIPO includes: Botswana, Gambia, Ghana, Kenya, Lesotho, Malawi, Sierra-Leone, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe.⁹²

The agreement on the creation of ARIPO and two protocols that member countries have enacted currently govern ARIPO. 93

The Harare Protocol established a Patent Documentation and Information Center in Harare, which provides its members with technological information available from patent and patent-related documentation and subsequent registration. The main objective of this protocol is to provide a partial solution to the dependent patent system by establishing an alternative scheme.⁹⁴

The protocol provides a procedure for registering, processing, granting, and administering of patents on behalf of member countries. ⁹⁵ The applicant sends his

⁸⁸ Id. at 768.

⁸⁹ Adewopo, *supra* note 78, at 765; James, *supra* note 77.

⁹⁰ Adewopo, *supra* note 78, at 765–66.

⁹¹ *Id.* at 766 (footnote omitted).

⁹² Adewopo, *supra* note 78, at 765 n.64; James, *supra* note 77.

⁹³ Adewopo, *supra* note 78, at 766 ("namely Harare Protocol and the Banjul Protocol").

⁹⁴ *Id*.

⁹⁵ *Id*.

or her application for registration to their respective national industrial property office where the member country will transmit the application to ARIPO. The standards of novelty and inventiveness, under the Harare Protocol, are comparable to the requirements found in the patent laws of WIPO/PCT and major industrialized nations. The property of the requirements found in the patent laws of WIPO/PCT and major industrialized nations.

D. South African Legislative Framework

South Africa enacted its patent system in 1978 with the Patents Act, 57. They also are members of the TRIPs Convention and are signatories to the treaty establishing WIPO. 99

1. Patentability Requirements

a. Statutory Requirement

Under the South African Patents Act, "an invention is capable of protection provided that it is new, inventive and is capable of use or application in trade or industry or agriculture." The Patents Act also distinguished inventions that may not be patentable and therefore are not inventions for purposes of the act:

Anything which consists of— (a) a discovery; (b) a scientific theory; (c) a mathematical method; (d) a literary, dramatic, musical or artistic work or any other aesthetic creation; (e) a scheme, rule or method for performing a mental act, playing a game or doing business; (f) a program for a computer; or (g) the presentation of information ¹⁰¹

b. Novelty Requirement

The novelty requirement is defined as anything that "does not form part of the state of the art immediately before the priority date of that invention." South Africa's novelty requirement is absolute, excluding cases where the "invention was disclosed, used or known without the knowledge or consent of the inventor

⁹⁶ *Id*.

⁹⁷ See Patent Cooperation Treaty art. 33(1–4), June 19, 1970, 28 U.S.T. 7645 [hereinafter PCT], available at http://www.wipo.int/pct/en/texts/pdf/pct.pdf; Adewopo, supra note 78, at 766.

⁹⁸ WORLD INTELLECTUAL PROP. ORG., STUDY ON PATENTS AND THE PUBLIC DOMAIN 58 (Apr. 27, 2011) [hereinafter STUDY ON PATENTS AND THE PUBLIC DOMAIN], available at http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_4/cdip_4_3_rev_study_inf_2.pdf.

⁹⁹ *Id*.

¹⁰⁰ *Id.*; *see* Patents Act, 57 of 1978 § 25(1) (S. Afr.) (as last amended in 2002), *available at* http://www.cipc.co.za/Patents_files/Patent_Act.pdf.

Id.; see STUDY ON PATENTS AND THE PUBLIC DOMAIN, supra note 98, at 58.

¹⁰² Patents Act, 57 of 1978 § 25(5) (as last amended in 2002), *available at* http://www.cipc.co.za/Patents_files/Patent_Act.pdf.

and reasonable technical trial or experiment by the applicant or patentee or the predecessor in title of the applicant or patentee." ¹⁰³

[P]rior disclosure before the date of filling of a patent application is deemed to destroy the novelty of the invention in question. Thus such an invention would be deemed to form part of the prior art and public domain. Section 27 of the Patents Act is instructive in respect of what is deemed to compromise the prior art. 104

2. Patentability Requirements and the Public Domain

Under the South African Patents Act, "[P]rior art comprises anything that has been made available to the public in any manner, prior to the date of application of a patent for the invention." Public, as defined by the Patents Act, "extends . . . outside the borders of South Africa, thus making the novelty requirement to be an absolute novelty requirement[]." South Africa provides no grace period for the purposes of patentability; novelty is absolute, except for where the use or disclosure is fraud against the rights of the patentee or applicant. The manner in which the novelty destroying disclosure is made to the public is irrelevant. Novelty destroying disclosures may include: written disclosures, sale or use, or oral descriptions (where the essence of the invention or the novel aspects are disclosed at a presentation, conference, speech, or in a meeting). South African case law has interpreted the predecessor to the Patents Act as determining any prior knowledge and use by a single person as sufficient evidence to be a novelty-destroying event.

3. CIPRO

From the enactment of the South African Patents Act 57 of 1978 until May 1, 2011, The Companies and Intellectual Property Registry Office (CIPRO) was the custodian of all patent applications filed within the Republic of South Africa. The Companies and Intellectual Property Commission (CIPC) now performs that

¹⁰³ STUDY ON PATENTS AND THE PUBLIC DOMAIN, *supra* note 98, at 58.

 $^{^{104}}$ Study on Patents and the Public Domain, *supra* note 98, at 58–59.

¹⁰⁵ *Id.* at 59.

¹⁰⁶ *Id*.

¹⁰⁷ *Id*.

¹⁰⁸ Id.

 $^{^{109}}$ STUDY ON PATENTS AND THE PUBLIC DOMAIN, supra note 98, at 59.

 $^{^{110}}$ Id

¹¹¹ See generally Patents Act, 57 of 1978 § 25(1) (S. Afr.) (as last amended in 2002), available at http://www.cipc.co.za/Patents files/Patent Act.pdf.

function.¹¹² Individuals may privately file provisional patent applications, however, only a patent attorney may file a non-provisional patent application and draft the patent specification.¹¹³

A provisional patent application may be filed where the invention has not been fully developed and tested. An individual that files a provisional patent application logged with CIPC, complete with a provisional specification, is afforded temporary protection for 12 months. Nationally, the provisional application may be extended for an additional three months, for a total of 15 months from filling the provisional application to complete development and testing of the invention and file the non-provisional patent application. If the applicant chooses to accept the three-month extension, the applicant forfeits international phase under the Patent Cooperation Treaty.

CIPC requires a patent attorney to file the non-provisional patent application for two reasons. First, a patent attorney is essential to draft a patent specification, specifically a definition and description of the invention, which is clear, coherent, and concise so that the inventor is provided the maximum protection in their invention. Secondly, South Africa is a non-examining country, meaning that CIPC does not investigate the novelty or inventive merit of the invention. Only the application is examined, for formalities only, and the substance of the product or process is not verified. The applicant is responsible for ensuring that the application is valid. However, this doesn't appear to be an affirmative duty on the applicant. But, if the applicant wishes to verify the validity of their patent, an international search is required to affirm novelty. Such a search may prevent

¹¹² See Companies Act, 71 of 2008 §§ 185–95 (S. Afr.) available at http://www.cipc.co.za/Companies_files/CompaniesAct71_2008.pdf.

¹¹³ Do I Need Assistance to File a Patent?, COMPANIES & INTELL. PROP. COMMISSION, http://www.cipc.co.za/Patents_FAQs.aspx (last visited Apr. 19, 2012).

First Patents Act, 57 of 1978 § 32(2) (S. Afr.) (as last amended in 2002) ("A provisional specification shall fairly describe the invention."), *available at* http://www.cipc.co.za/Patents_files/Patent_Act.pdf.

¹¹⁵ Do I Need Assistance to File a Patent?, supra note 113.

¹¹⁶ See id.

¹¹⁷ See id.

¹¹⁸ See Patents Act, 57 of 1978 § 32(3) (S. Afr.) (as last amended in 2002) ("A complete specification shall"), available at http://www.cipc.co.za/Patents_files/Patent_Act.pdf.

See Registration Procedure, COMPANIES & INTELL. PROP. COMMISSION, http://www.cipc.co.za/Patents_RegProcedure.aspx (last visited Apr. 19, 2012) (requiring the inventor to perform a search to confirm novelty).

¹²⁰ See id. ("If all the formalities have been complied with, the application is accepted."). ¹²¹ See generally Patents Act, 57 of 1978 (S. Afr.) (as last amended in 2002), available at

http://www.cipc.co.za/Patents_files/Patent_Act.pdf.
¹²² *Id.* § 25.

future litigation for the applicant's patent infringement of a pre-existing patent, may prevent a finding of invalidity of the applicants patent for lack of novelty, and is necessary for any applicant who wishes to commercialize an invention in a foreign country under the PCT. ¹²³

E. Patent Cooperation Treaty

The Republic of South Africa joined the PCT on March 16, 1999. 124 "Consequently, nationals and residents of the Republic of South Africa are entitled to file international applications under the PCT "125 South Africa's entrance into the PCT also enables other member countries to file international applications designating and electing a national phase in South Africa. 126

F. World Trade Organization

The World Trade Organization (WTO), formed on January 1, 1995 under the Marrakesh Agreement, is a multilateral institution charged with administering trade rules among member countries and is the successor to the General Agreement on Tariffs and Trade (GATT). The WTO:

[S]erves as a forum for trade negotiations, resolves trade disputes, monitors the national trade policies of its 153 member countries, provides technical assistance and training for developing countries, and cooperates with other international intergovernmental organizations. 128

As successor to the GATT, the WTO emerged from a series of trade negotiations . . . conducted under the auspices of the GATT. Countries participating in the Uruguay Round of GATT created the WTO and in the process also achieved a major revision of the original GATT. Established just after World War II, the GATT was widely perceived to be ill-equipped to address the complexities of a modern global market.

The original GATT primarily governed the trade of goods. The Uruguay Round set forth new rules to govern trade in services, relevant aspects of intellectual property and dispute settlements, and also included trade policy reviews within its negotiated agreements. As members of the WTO, countries receive assurances that their exports will be treated fairly in foreign markets in

¹²³ See generally id.

¹²⁴ Patent Cooperation Treaty Update, USPTO (Jan. 13, 1999),

http://www.uspto.gov/web/offices/com/sol/og/1999/week06/pattrty.htm.

¹²⁵ *Id*.

¹²⁶ *Id*.

¹²⁷ Erika George, *The Human Right to Health and HIV/AIDS: South Africa and South-South Cooperation to Reframe Global Intellectual Property Principles and Promote Access to Essential Medicines*, 18 IND. J. GLOBAL LEGAL STUD. 167, 173 (2011).

¹²⁸ *Id.* at 173–74 (footnotes omitted). The article continues:

1. TRIPs Agreement

The Agreement on Trade related Aspects of Intellectual Property Rights (TRIPs), negotiated in 1994, is an international agreement administered by the World Trade Organization (WTO). 129

The TRIPs Agreement includes rules governing various forms of intellectual property including: copyrights, patents, trademarks, geographical names, and others. 130 Due to widely varying standards of protection and enforcement across the globe, the TRIPs Agreement sets a minimum threshold of intellectual property protection that all members must meet. 131 This minimum threshold also requires member states to grant intellectual property protection without discrimination against imported products. 132

Prior to the TRIPs Agreement, countries were only obligated to protect foreign intellectual property to the same extent that it protected local intellectual property. 133 The TRIPs agreement no longer allows member states to set different levels of protection, unless that level of protection is greater than the minimum threshold. 134

The WTO in drafting the TRIPs agreement enumerated its objectives for the agreement 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

exchange for their commitment to extend fair treatment to imports into their own domestic markets

During the Uruguay Round, developing countries negotiated some flexibility in implementing their commitments under the WTO. Over seventy-five percent of WTO members are developing or least-developed countries. Special provisions in certain WTO agreements recognize the challenges developing countries confront and permit longer time periods for such countries to implement agreements and commitments. Also, there are measures to encourage increased trading opportunities for developing members, and all WTO members are obligated to respect the trade interests of developing members.

Id.
129 TRIPs, supra note 67.

¹³⁰ See id.; see also George, supra note 127, at 174.

¹³¹ George, *supra* note 127, at 174–75 (footnotes omitted).

¹³² Id. at 174 (footnote omitted).

¹³³ *Id.* at 175.

¹³⁴ See TRIPs, supra note 67: see also George, supra note 127, at 175.

in a manner conducive to social and economic welfare, and to a balance of rights and obligations. 135

a. DOHA Declaration

A special session of the TRIPs council was called in 2001 due in part to: The Pharmaceutical Manufacturers' Association of South Africa's (PMA) lawsuit against the Medicines Act, 136 the opposition to PMA's lawsuit by South Africans living with HIV/AIDS, ¹³⁷ and the momentum generated by a global movement for Human Rights¹³⁸ combined with the inquires by United Nation agencies regarding the connection between intellectual property and public health. George states that:

Talks at the TRIPs Council eventually resulted in the adoption of the Declaration on the TRIPs Agreement and Public Health at the WTO's ministerial meeting in Doha. Commonly called the Doha Declaration, the Declaration . . . is primarily a product of an alliance of countries and communities in the Global South and largely reflects the perspectives of developing countries. 140

¹³⁵ TRIPs, *supra* note 67, art. 7.

¹³⁶ See George, supra note 127, at 182–183 (citing Pharm. Mfrs. Ass'n v. President of the Republic of S. Afr., Case No. 4183/98, High Court of South Africa (Transvaal Provincial Division). The PMA, a coalition of the local subsidiaries of several major multinational pharmaceutical corporations,

brought suit in the High Court in Pretoria challenging the South African government's legislative efforts to increase access to medicine. PMA argued that the government's proposed reforms in the Medicines Act would constitute a violation of their rights under the South African Constitution. The Association also argued that South Africa's statute was in breach of the government's TRIPs Agreement obligations.

Id.

 $^{^{137}}$ Id. at 183. The human rights opposition to PMA's suit was lead by The Treatment Action Campaign (TAC). TAC asserted "that industry efforts to block legislation intended to increase access to medicines would threaten their rights to health, dignity, and life." Id.

¹³⁸ *Id.* at 188.

¹³⁹ See U.N. High Comm'r for Human Rights, Economic, Social and Cultural Rights: The Impact of the Agreement on Trade-Related Aspects of Intellectual Property on Human Rights: Rep. of the High Comm'r, ¶ 43, U.N. Doc. E/CN.4/Sub.2/2001/13 (June 27, 2001) (finding that the effect of patents on drug price affordability is significant because drugs with generic substitutes were much cheaper than those without a generic counterpart.); see also George, supra note 127, at 188. George, *supra* note 127, at 188.

The Doha Declaration asserts that TRIPs member governments must implement and interpret the TRIPs agreement in a way that promotes public health through access to existing medicines and the creation of new medicines.¹⁴¹

We agree that the TRIPs Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPs Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPs Agreement, which provide flexibility for this purpose. 142

The Doha Declaration further outlines three flexibilities which member states are entitled by right to exercise. Leach member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency. Finally, the effect of the provisions in the TRIPs Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge 146

III. THE AFFECT OF SOUTH AFRICA'S PATENT SYSTEM ON THE COUNTRY'S DEVELOPMENT

The current state of affairs in the Republic of South Africa in some regards, such as access to essential medicines, has improved significantly in the recent decade. However, continued access to essential medicines is not likely to

¹⁴¹ *Id.* at 189.

¹⁴² World Trade Organization, Ministerial Declaration of 14 November 2001, ¶ 4, 41 WT/MIN(01)/DEC/2, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration].

¹⁴³ See generally Id. \P 5(b).

¹⁴⁴ *Id*.

¹⁴⁵ Doha Declaration, *supra* note 142, ¶ 5(c).

¹⁴⁶ Doha Declaration, *supra* note 142, ¶ 5(d).

¹⁴⁷ See supra Part II.B.3.a.

continue past 2016 and prices may once again rise to the level seen prior to 2000 for antiretroviral treatments necessary for those with HIV/AIDS. 148

The extreme poverty that South Africa has faced has only gotten worse as more of the population slips below the poverty line. Though this may not be directly attributed to South Africa's patent system or their signatory status to the TRIPs agreement, they certainly are contributing factors to South Africa's economic stability.

Finally, the TRIPs agreement must be scrutinized for its favoritism of developed countries and how this favoritism may have affected South Africa's socioeconomic development.¹⁵¹

A. HIV/AIDS Epidemic

As previously discussed, much progress has been made over the last decade to reduce the cost of essential medicines, for example, HIV/AIDS antiretroviral treatments, and in-turn increase developing countries' accessibility to them. However, even with the strides made, such drugs are still largely out of reach for the 25 million South Africans who live below the poverty line. And to make matters worse, one of the largest factors that has driven essential medicine prices down in developing countries will largely cease to exist by 2016.

Under the TRIPs agreement, signed in 1995, developing countries were given a ten-year transition period in which to comply with the agreement. Particularly important for this note are the agreement's regulations on developing generic drugs. This allowed developing countries, such as India, to continue to develop generic drugs until 2005. The agreement also allowed least-developed signatory countries until 2016 to comply. However, the 2016 date is likely insignificant as 80% of the world's HIV medicines are made in India, to continue to developed signatory countries until 2016 to comply. However, the 2016 date is likely insignificant as 80% of the world's HIV medicines are made in India, to continue to developed signatory countries until 2016 to comply. However, the 2016 date is likely insignificant as 80% of the world's HIV medicines are made in India, to continue to developed signatory countries until 2016 to comply. However, the 2016 date is likely insignificant as 80% of the world's HIV medicines are made in India, to continue to developed signatory countries until 2016 to comply. However, the 2016 date is likely insignificant as 80% of the world's HIV medicines are made in India, to continue to developed signatory countries until 2016 to comply.

¹⁴⁸ See infra Part III.A; see supra II.B.3.a.

¹⁴⁹ See supra Part II.B.3.b.

¹⁵⁰ See infra Part III.B.

¹⁵¹ See infra Part III.C.

¹⁵² See supra Part II.B.3.a.

¹⁵³ See supra Part II.B.3.a-b.

¹⁵⁴ See supra Part II.B.3.a.

¹⁵⁵ See supra Part II.B.3.a.

¹⁵⁶ Reducing the Price of HIV/AIDS Treatment, supra note 66.

¹⁵⁷ India's generic pharmaceutical industry under threat from EU pact, ASIAN BUSINESS DAILY, http://asianbusinessdaily.com/2012/02/indias-generic-pharmaceutical-industry-under-threat-from-eu-pact/ (last visited Apr. 19, 2012).

significantly, likely adjusting to the reduced availability of generic drugs in the marketplace. In 1996, the cost of first line antiretroviral treatments was over USD \$10,000 per person per year. By mid-2001, generic triple combination therapy treatments cost as little as USD \$295 per person per year. Between 2004 and 2008, first line antiretroviral treatments were available for USD \$64 per person per year. In 2011, after the compliance of most developing countries to the TRIPs agreement, a tenofovir based treatment (a newer generation of antiretroviral treatment for AIDS) cost \$159 per person per year. This data suggests that as newer generations of AIDS treatments come on the market, without downward price pressure exerted by generic pharmaceutical companies, brand pharmaceutical companies will continue to price pharmaceuticals as the market allows.

B. Extreme Poverty

With the poverty gap growing faster than the economy, it is clear that South Africa's economy is moving in the wrong direction. There is no evidence of a direct link between South Africa's shrinking economy and its patent system or its international patenting stance. However, for the purposes of this article, it will be assumed that South Africa's patent system is at least a contributing factor to the country's current economic condition.

C. The TRIPs Agreement Favors Developed Nations

Prior to the Uruguay Round of the GATT, developing member countries were strongly against the development of intellectual property protection. The developing countries desired the GATT to remain strictly an international trade agreement, as their primary concern was access to the markets of industrialized nations. However, the developed member countries saw a great need for enhanced intellectual property protection, and used their leverage to achieve the TRIPs Agreement. The trade-off that took place was this: developing countries

¹⁵⁸ Reducing the Price of HIV/AIDS Treatment, supra note 66.

¹⁵⁹ *Id*.

¹⁶⁰ *Id*.

¹⁶¹ Id.

¹⁶² See supra Part II.B.3.b.

¹⁶³ Nadia Natasha Seeratan, *The Negative Impact of Intellectual Property Patent Rights on Developing Countries: An Examination of the Indian Pharmaceutical Industry*, 3 SCHOLAR 339, 352–53 (2001).

¹⁶⁴ *Id*. at 353.

¹⁶⁵ Gerald J. Mossinghoff, *National Obligations Under Intellectual Property Treaties: The Beginning of a True International Regime*, 9 FED. CIR. B.J. 591, 598 (2000) (stating that the U.S. engaged in linkage-bargain diplomacy, a negotiation tactic in which developing countries received

received greater access to the markets of industrialized countries in exchange for the developing countries receiving enhanced international intellectual property laws in the form of the TRIPs Agreement. "For developing countries, this trade-off [was] potentially dangerous to their well being," particularly as it relates to pharmaceutical patents. The result: "the developing countries' dedication to facilitate their economic growth and independence [was] inhibited by the overenforcement of intellectual property laws" which favored the developed nations. "Essentially, these countries were forced to either agree to the version of GATT including TRIPs, or be excluded from the benefit of GATT entirely. Unfortunately, the trade-off placed developing countries and public health policy at the whim of the developed countries"

IV. PATENT SYSTEM BASED SUGGESTIONS FOR IMPROVEMENT OF SOUTH AFRICA'S SOCIOECONOMIC SITUATION

A. A Balanced TRIPs Agreement

The TRIPs agreement is in need of a better balance between rich and poor signatory countries. As discussed previously, the TRIPs agreement was written by developed countries for the benefit of developed countries. The developing countries had no choice but to agree to TRIPs if they wanted continued access to the markets of industrialized nations. In the TRIPs agreement, there is a need for the inclusion of flexible provisions for developing countries, particularly in regards to protecting public health. The following sections apply the Seeratan analysis to South Africa's socioeconomic situation.

1. Authority to Amend or Modify the TRIPs Agreement

Under Article 71 of the TRIPs Agreement:

The council for TRIPs shall review the implementation of this Agreement after the expiration of the transitional period referred to in paragraph 2 of Article 65. The Council shall, having regard to the experience gained in its implementation, review it two years after that date, and at identical intervals thereafter. The Council

greater access to industrialized countries); *see also* Seeratan, *supra* note 163, at 353 (stating that developed countries received enhanced international IP laws via the TRIPs Agreement).

¹⁶⁶ Seeratan, *supra* note 163, at 353.

¹⁶⁷ Id

¹⁶⁸ *Id.* at 354.

¹⁶⁹ Seeratan, *supra* note 163, at 360 (footnote omitted).

See supra Part III.C.

¹⁷¹ See supra Part III.C.

¹⁷² Seeratan, *supra* note 163, at 402.

may also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement.¹⁷³

The transitional period ended in 2005, therefore under Article 71 the Council has the authority to review the agreement with "regard to the experience gained in its implementation" and "in the light of any relevant new developments which might warrant modification." Certainly, a country's inability to suppress an epidemic like HIV/AIDS due to the country's extreme poverty and high cost of access to medicines is a "relevant new development" that deserves attention and flexibility under TRIPs. ¹⁷⁵

2. Decrease Patent Term

Decreasing the 20-year patent term required for pharmaceuticals in the TRIPs Agreement would greatly benefit developing countries. The current term length greatly benefits brand pharmaceutical corporation profits. A shorter term length would allow generic drug manufacturers to enter the market earlier and to produce and sell generics at a fraction of the price of brand pharmaceuticals, allowing low-income countries to access these critical medicines much earlier.

However, it is important to note the importance of a proper balance between pharmaceutical patent protection and access to medicines for developing countries. Though the immediate need to get affordable pharmaceuticals to developing countries is pressing, it is critical that we not detriment the future for the betterment of the present. If the patent term for pharmaceuticals is over-reduced, we will get affordable generic medicines to developing countries faster, but this is not without cost.

The danger of reducing patent term is the potential for under-funding future pharmaceutical advancements. Generic pharmaceutical companies are able to produce medicines below brand costs because generic companies' research and development costs are significantly less. Generic companies rely on brand pharmaceutical research and once patent protection has expired, they reverse engineer the composition of the drug and manufacture it at significant savings, some of which they pass on to consumers. Brand pharmaceutical companies rely on their profits from existing treatment generations in order to fund current

¹⁷³ TRIPs, *supra* note 67, art. 71(1).

¹⁷⁴ *Id.*; *see also* Seeratan, *supra* note 163, at 402 (discussing two changes needed immediately: reducing the 20 year patent term, and extending the transition period for developing nations).

¹⁷⁵ *See supra* Part II.B.3.a–b.

http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm (last visited Apr. 12, 2012).

and future research. The cost to bring a new drug to market in 2010 was estimated as high as \$1.8 billion.¹⁷⁷ The danger is that at a certain reduced patent term, a pharmaceutical company may decide not to develop a drug at all due to their projected inability to recuperate the cost of development. In which case, the world would be trading affordable drugs now for critical life-saving drug advancements in the future.

3. Promote Basic Human Rights

Health and essential medicines are basic human rights. Since the implementation of the TRIPs agreement, many human rights activists have asserted that the TRIPs provision on the patenting of pharmaceuticals violates basic human rights by compromising the ability of poor countries to access essential medicines. In August of 2000, a United Nations panel indicted the WTO for failing to respect human rights in the implementation of TRIPs, specifically its failure in making necessary medicines for deadly diseases affordable to poor nations. In the implementation of TRIPs, specifically its failure in making necessary medicines for deadly diseases affordable to poor nations.

However, the fault may not fall completely on the shoulders of the WTO. The TRIPs Agreement does contain two Articles that were intended to reflect the needs of developing countries, Articles 8 and 27. Article 8 promises to protect public health, which "should be utilized to demand that there is an essential right to health, and thus essential medicines should be made available, regardless of patent laws." Article 27 "contains a public health exception to the patent requirement which includes the protection of human life or health." The public health exception, if used, would allow a country with legitimate health concerns to deny a patent on a particular drug. The question that remains is why countries, such as South Africa, have not relied on these Articles to protect the public health of their countries. Perhaps developing countries are fearful of backlash from developed countries.

Providing access to essential medicines and guarding basic human rights to life can be accomplished in a manner consistent with the TRIPs Agreement. Exceptions to patent protection on pharmaceuticals for essential medicines, under

¹⁷⁷ Steven M. Paul et al., *How to Improve R&D Productivity: The Pharmaceutical Industry's Grand Challenge*, 9 NATURE REVIEWS DRUG DISCOVERY 203, 204 (2010), *available at* http://www.nature.com/nrd/journal/v9/n3/full/nrd3078.html.

¹⁷⁸ Seeratan, *supra* note 163, at 403–04.

¹⁷⁹ *Id.* at 404.

¹⁸⁰ *Id*.

¹⁸¹ *Id.*; see also TRIPs, supra note 67, art. 8.

¹⁸² Seeratan, supra note 163, at 404; see also TRIPs, supra note 67, art. 27(2).

¹⁸³ TRIPs, supra note 67, art. 27(2); see also Seeratan, supra note 163, at 404.

the TRIPs Agreement, can be accomplished through parallel imports and compulsory licenses.

b. Parallel Imports

Under a parallel imports solution, a country in need of cheaper priced drugs, instead of purchasing the drugs from the country of origin, purchases the drugs where they are available at a cheaper price. This solution is allowable under the theory of Patent Exhaustion, and cannot be challenged at the WTO as it does not violate international law, including a country's obligation under TRIPs. 184

c. Compulsory Licenses

"Compulsory licenses allow a local pharmaceutical company to manufacture generic copies of patented pharmaceuticals at lower prices by forcing multinational corporations to issue a license in exchange for a reasonable royalty." Compulsory licenses fall in accordance with the national emergency exception in Article 31 of TRIPs. However, developing countries that attempt to implement compulsory licenses face diplomatic pressure from the pharmaceutical industry and developed countries. The result is that Article 31 is not utilized as intended, due to fear of reprisal. This bullying must stop. Pharmaceutical companies should not be allowed to dictate whether a developing country chooses to utilize compulsory licensing.

One defense against this bullying is to amend the TRIPs Agreement such that a country that chooses to use compulsory licenses for a patent in order to cope with a national emergency has no burden of proof. Effectively, this shifts the burden to the patent holder to prove that there is no emergency.

¹⁸⁴ Seeratan, *supra* note 163, at 405–06. Under patent exhaustion theory, once a country/producer has sold a product to another country, it has received the benefit of the patent and its rights are exhausted. Therefore, the country that purchased the product may dispose of it as they please, including resale to another country. *Id*.

¹⁸⁵ *Id.* at 406.

¹⁸⁶ TRIPs, *supra* note 67, art. 31(b) (waiving requirement to obtain authorization from right holder during national emergency); *see also* Seeratan, *supra* note 163, at 407.

¹⁸⁷ Tina Rosenberg, *Look at Brazil*, N.Y. TIMES, Jan. 28, 2001, *available at* http://www.nytimes.com/2001/01/28/magazine/look-at-brazil.html?pagewanted=all&src=pm (Brand name pharmaceutical companies have long financed both political parties in the United States. Therefore, it is likely that the pharmaceutical industry would use this influence to prevent such compulsory licenses from going unnoticed.); *see also* Seeratan, *supra* note 163, at 406—07.

¹⁸⁸ Larry Elliott, *Putting Profit Before People*, CANBERRA TIMES, Feb. 19, 2001, at A11; *see also* Seeratan, *supra* note 163, at 407.

B. Work Requirements on Pharmaceutical Patents and Territoriality Limitations

Work requirements require an invention to be manufactured domestically in order to receive patent protection. If the patented invention is manufactured outside of the developing country, to receive patent protection within the country a petition must be filed requesting a license from the government to manufacture the invention domestically. Prior to the TRIPs Agreement, many developing countries imposed work requirements. However, under Article 27(1) of the TRIPs Agreement, work requirements are banned because they prevent patents from being enjoyed whether the products are locally produced or imported. Though work requirements would greatly promote industry within South Africa, the WTO's economic sanctions for violation of the TRIPs Agreement would likely negate any benefit that would come from the work requirements.

National patent protection is limited territorially. That is, the patent right only has effect in the jurisdiction in which it has been granted. One method for developing countries to play industrial "catch-up" with the developed world is to apply territoriality limitations upon a certain industry, e.g., the chemical industry, which prevents patenting in that industry for a period of years. These territoriality limitations would prevent non-domestic industries from applying for and asserting their patents nationally, which otherwise would slow innovation within that country in the given industry.

C. Elimination of Unilateral Sanctions by the United States

The WTO in its development of the TRIPs Agreement created the Dispute Settlement Body (DSB) as a system to enforce the TRIPs' intellectual property laws. Though the DSB over time has proven not to be a perfect system, it does have the benefit of facial neutrality. Even with the DSB in place, the United States amended and continued use of their Special 301 laws, laws enacted to police intellectual property law throughout the world. The Special 301 law places countries that fail to issue pharmaceutical patents on a watch list.

¹⁸⁹ Seeratan, *supra* note 163, at 407.

¹⁹⁰ *Id*.

¹⁹¹ TRIPs, supra note 67, art. 27(1); see also Seeratan, supra note 163, at 407.

¹⁹² Understanding on Rules and Procedures Governing the Settlement of Disputes art. 2(1), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401 [hereinafter DSU].

¹⁹³ Seeratan, *supra* note 163, at 408.

¹⁹⁴ *Id.* "[T]he United States claims that they amended Special 301 to ensure that the measure would not conflict with TRIPs and the DSB" *Id.*

¹⁹⁵ *Id*.

¹⁹⁶ *Id*.

Because of this watch list, developing countries may be bullied into issuing pharmaceutical patents out of fear that being placed on the U.S. watch list will discourage foreign investment and thus act as a sanction. The unilateral nature of the Special 301 laws appears to be in bad faith with the TRIPs Agreement. Agreement and developing countries should not be allowed under the TRIPs Agreement and developing countries should resist such unilateral pressures. The DSB was created to prevent the need for such biased international property law enforcement systems and therefore developing countries cannot and should not be expected to trust a system that is policed solely by one country. The TRIPs Agreement needs to be amended to clearly address and renounce the existence of such unilateral international property law enforcement regimes.

D. Price Controls (Tiered Pricing)

The Republic of South Africa has successfully used tiered pricing ¹⁹⁹ to greatly reduce the cost of antiretroviral treatments within its country. ²⁰⁰ However, the prices of these treatments are still not affordable for the majority of South Africa's population. ²⁰¹ Continued negotiations with the pharmaceutical industry is needed to sufficiently address their concerns that low priced drugs provided to developing countries will not be re-imported to the industrialized countries, thus undermining the existing cost structures. ²⁰²

E. Increased Global Movement for Human Rights

Lead by groups such as TAC, The Treatment Action Campaign, the global movement for human rights has resulted in decreasing the pressure on essential medicine costs in developing countries. The increased attention on human rights concerns in developing countries, greatly accredited to organizations such as TAC and the Global Access to Medicines Campaign, combined with bad publicity shed on pharmaceutical companies in relation to the South African PMA

¹⁹⁷ *Id*.

¹⁹⁸ Id

¹⁹⁹ Tiered pricing is "a system of differential pricing, where pharmaceutical companies charge developing countries less than advanced industrialized countries to ensure the patented technologies are not priced at unreasonable levels." Secretar, *supra* note 163, at 408—09.

²⁰⁰ See supra Part II.B.3.a.

²⁰¹ See supra Part II.B.3.a.

²⁰² Seeratan, *supra* note 163, at 409.

²⁰³ See supra Part II.F.1.a; George, supra note 127, at 193. "The cost of a triple therapy combination of antiretroviral drugs that cost the equivalent of USD \$450 dropped to \$125 in South Africa." George, supra note 127, at 193. "[T]he number of HIV-positive women receiving antiretroviral therapy increased from 76,000, at the end of 2004 to 251,400 at the end of 2006," sparing 47,700 infants from infection. *Id.* (internal quotations omitted). "In South America, prices fell by fifty-four percent in fourteen countries." *Id.*

case have all played a vital role in decreased pharmaceutical costs in developing countries. 204

While the human rights movement has made considerable inroads toward affordable essential medicines to developing countries, without continued effort these movements may not ensure a sustainable balance between pharmaceutical companies intellectual property rights and developing countries obligations to afford their people basic human rights.²⁰⁵

V. CONCLUSION

The Republic of South Africa has made significant strides over the past decade to improve the accessibility of essential medicines to its people. However, the country is still in dire turmoil, essential medicines are still out of reach of the majority of the country's people and the economic outlook for its people has actually worsened in the past half-decade. Though South Africa could continue on their current path—which has shown results for human rights, but little for the country's economic condition—the country needs to seriously consider more drastic measures. Some of these drastic measures are suggested above; many would be to the detriment of international relationships. Regardless, South Africa requires a proper balance between international relations and internal government action focused on the betterment of those living within South Africa.

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²⁰⁴ George, *supra* note 127, at 193.