2004


Matthew Leis

Follow this and additional works at: http://scholarlycommons.law.hofstra.edu/jibl

Recommended Citation

This Note is brought to you for free and open access by Scholarly Commons at Hofstra Law. It has been accepted for inclusion in Journal of International Business and Law by an authorized administrator of Scholarly Commons at Hofstra Law. For more information, please contact lawcls@hofstra.edu.
DEATH BY TREATY:
SOUTH AFRICA’S MEDICINES AND RELATED SUBSTANCES
AMENDMENT ACT OF 1997 AND THE AGREEMENT ON TRADE
RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

By: Matthew Leis

1. INTRODUCTION

For some nations, Acquired Immune Deficiency Syndrome (AIDS) has become the top predator; one which feeds on human prey. The HIV/AIDS epidemic has exploded across much of Africa and the danger is escalating quickly. South Africa alone is believed to have one in five adults infected with the HIV virus. It is also estimated that over 91,000 babies were infected with HIV during 2002 alone. These babies were infected via mother to child transmission which is almost completely preventable with the administration of the proper medication. This epidemic is mirrored throughout most of the world, but is especially prevalent in third world countries where the population is poor and often uneducated. A short list of other countries where HIV is particularly rampant include Brazil, India, Thailand, and many of the other nations in Sub-Saharan Africa.

Unfortunately, medicine to combat the HIV virus is very expensive. Often the patented or “designer” versions of these drugs can cost an individual around $15,000 to $20,000 per annual treatment in the United States; comparatively, the per capita income in South Africa is only $6,800. Another problem in medicating the infected public is that most countries lack the infrastructure and technology to produce medicines internally.

Thus, many developing or less developed countries are faced with an HIV epidemic without the economic or industrial means to combat this growing epidemic.

*Mr. Leis is a student at Hofstra University School of Law. He would like to thank Professor Julian Ku for his guidance and direction with this note. He dedicates this note to his parents, Thomas and Jerilyn Leis, for their love, encouragement and support.

1 Marilynn Marchione, AIDS Continues Spreading: 20% of Adults in South Africa Have Virus, U.N. says (2003), at http://www.jsonline.com/alive/news/nov03/188110.asp (last visited Apr. 15, 2004). (It is important to note that the 20% infection rate is only an estimate because many of the people infected with the HIV virus do not report their illness.).


3 Avert.org, supra note 2. (The problem here is two fold. First, the drugs which would prevent mother to child transmission cost too much for the poor to afford. Second, many of the mothers are uneducated, and either do not get tested for the HIV virus, or are unaware of the preventive measures available; that is, if they can afford them.).

4 Duncan Reekie, South Africa’s Battle With AIDS and Drug Prices (2000), at http://www.ncpa.org/ba/ba334/ba334.html (last visited Apr. 15, 2004). (Although drug prices are much lower in South African, most of the population still cannot afford them. For example, two medications commonly taken by AIDS patients are AZT and Didanosine. A United States customer will pay approximately $10.12 for AZT and $7.25 for Didanosine, whereas a South African customer will pay approximately $2.16 and $2.80 respectively.)
problem. This shortage, or in the cases where the drugs are available, the simple inability of the population to afford the medication, leads people to cry for immediate relief.

Some governments have responded to this pressure by importing much cheaper generic versions of the expensive patented HIV medicines which can cost approximately $350 per annual treatment. At a meeting in 2001, all of the World Trade Organization members agreed (including the United States) that public health concerns should override certain patent rights. However, the implementation of this decision has proven to be much more difficult than previously thought.

In an attempt to combat the suffering of people with HIV, the government of South Africa enacted the Medicines and Related Substances Act of 1997 and subsequent Medicines and Related Substances Amendment Act of 2003, in order to grant the South African Minister of Health the power to “prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public.” This Act provoked a strong response from the world’s pharmaceutical industry, causing thirty nine pharmaceutical manufacturers to bring suit against South Africa in 1998. The plaintiffs claimed that South Africa violated the Trade Related Intellectual Property Rights (TRIPs) agreement when the country changed its law (adopting the Medicines Amendment Act of 1997).  

See Trade and Development in the World Trade Organization, at http://www.wto.org/english/tratop_e/develop_e/develop_e.htm (last visited Apr. 15, 2004). (This link will explain the designations: “developed, developing, and least developed” which are coined by the WTO and will be used throughout this note. A nation has the power to decide for themselves what status their country has achieved. The majority of WTO members consider themselves developing countries.).


Liz Highleyman, AIDS Drug Patents and Pricing Remain at Issue, Bay Area Reporter (2001), at http://www.aegis.com/news/bay/2001/BR010406.html (last visited Apr. 15, 2004). (This suit was eventually dropped and a settlement was reached due in no small part to the negative public image the pharmaceutical companies were developing.).

Tim Westmoreland, Interview with Timothy Westmoreland, Professor of Law and Public Policy, Georgetown University, 8 GEO. PUB’L POL’Y REV. 64 (2003). (Specifically, plaintiff’s argued a multitude of violations, but this article focuses on §15(C) of the 1997 Act.) See also Notice of Motion in pharmaceutical case, available at http://www.cptech.org/ip/health/usa/pharmsuit.html (last visited Apr. 15, 2004). (This website lists the plaintiff’s in the pharmaceutical case. Also, the original complaint had forty two plaintiffs as listed on this website)
The pharmaceutical manufacturers argue that they are in a tough predicament. If they donate or severely discount the cost of HIV medication exported to countries in need, they would lose profits which are then invested back into their research and development departments. Typically, it costs approximately $500 million to develop a new drug, and most drugs do not see a return of this initial expense. The pharmaceutical industry argues that it is unfair and illegal to force them to lose profits from these patented inventions because the major underlying policy of patent systems is to give the inventor a monopoly for a limited time as a quid pro quo for both public disclosure and the initial cost of developing the invention. If manufacturers are subsequently denied profit, they will be unwilling and unable to make the initial investment.

All developed countries, and most developing or least developed countries have intellectual property (IP) law already in place to govern their domestic affairs. However, as the number of nations engaged in world trade through the WTO increases, the complexities of combining the various legal systems creates conflict. Also, this complexity escalates exponentially when the human struggle against disease is added to the mix. Thus, modern IP law is being shaped by the clash of individual member nations’ legal systems with pressure added from certain populations suffering from epidemics.

II. INTELLECTUAL PROPERTY GENERAL HISTORY AND BACKGROUND

Patent laws function to advance technology under the theory that granting patentees the right to exclude others from practicing the patented invention for a limited time benefits society as a whole. In fact, this right is one

---

12 See, Qualitex Co. v. Jacobson Products Co., Inc., 514 U.S. 159, 164 (1995). See also, Kara Bombach, Can South Africa Fight Aids? Reconciling the South African Medicines and Related Substances Act with the TRIPs Agreement, 19 B.U. INT’L L.J. 273, 281 (2001) (Most pharmaceuticals only have significant marketability for approximately 10 years because of the invention and release of better drugs (having less side effects) usually occurs at around this time. Thus, for about half of the patent life (term of 20 years) the patent acts only as a deterrent rather than a reward for efforts.).
13 Kara Bombach, Can South Africa Fight Aids? Reconciling the South African Medicines and Related Substances Act with the TRIPs Agreement, 19 B.U. INT’L L.J. 273, 281 (The United States government actually subsidizes much of the AIDS research so that pharmaceutical companies incur a small percentage of the actual initial costs. It can be argued that the pharmaceutical industry looses very little from discounting prices or the implementation of some other price reduction mechanisms because the poor populations would not be able to afford these medicines anyway.).
14 See Trade and Development in the World Trade Organization, supra note 5.
15 See Structure of the World Trade Organization, at http://www.wto.org/english/thewto_e/whatis_e/inbrief_e/inb02_e.htm (last visited Apr. 15, 2004). (The WTO has nearly 150 members, accounting for over 97% of world trade. Around 30 others are negotiating membership.).
of the few specifically enumerated rights in the United States Constitution.\textsuperscript{16} The temporary monopoly granted to an inventor serves many overlapping purposes.

First, patent rights allow a patentee to disclose his invention to the public while retaining exclusive right to practice that invention.\textsuperscript{17} This allows the public to learn from the invention and improve upon it. Public disclosure in conjunction with a temporary monopoly advances science — and in turn society — by stopping others from practicing the patented invention, thereby forcing them to go out and make a “better mouse trap” if they wish to go into the “mouse trap” business. The patent system thereby promotes scientific progress by requiring creative advancement to enter certain markets.

Second, patent rights give an inventor economic incentive to invest time and money into a project.\textsuperscript{18} The inventor is more willing to go through great expense if he knows his efforts will be rewarded upon completion.\textsuperscript{19} The temporary monopoly makes it possible for companies to expend large amounts of money in research and development.\textsuperscript{20} Companies would be extremely reluctant to develop new products if their initial expense for doing so was not recoupable.

Critics of the pharmaceutical industry acknowledge the above arguments, but deny their impact on the industry’s profit margin. For example, African markets collectively comprise only 2\% of the global market for pharmaceuticals.\textsuperscript{21} In fact, taken together, all developing nations comprise only 10\% of the global market for pharmaceuticals.\textsuperscript{22} Furthermore, most pharmaceuticals are only profitable for approximately ten years, as contrasted with the twenty year monopoly granted by most patent systems.\textsuperscript{23} This means that for half of the patent’s life it acts as a deterrent rather than a reward for time and money invested. Upon the foregoing it can be argued that the second ten year period for pharmaceutical patents acts only to prevent generic, low cost equivalents depriving those in need of affordable medicine.\textsuperscript{24}
III. EXAMINATION OF TRIPS AGREEMENT AND WTO DISPUTE RESOLUTION PROCEDURES

The Uruguay Round was by all accounts the largest trade negotiation ever.\textsuperscript{25} It took twice the original schedule (seven and a half years total) to come to agreements on almost all aspects of international trade.\textsuperscript{26} For the purposes of this Note, the two most important agreements made at the Uruguay Round were the creation of the World Trade Organization (WTO) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). With the creation of the WTO, the General Agreement on Tariffs and Trade (GATT) was replaced as the head international trade organization, although, much of the 1947 GATT provisions still exist and provide a framework for global trade.\textsuperscript{27}

The TRIPs agreement attempts to create uniform international intellectual property rights linked inextricably with international trade.\textsuperscript{28} To achieve this difficult goal, the agreement sets out three main principles: (1) a minimum standard of protection provided by each WTO member nation for patents, copyrights, and trademarks; (2) procedures for domestic enforcement of intellectual property rights; and (3) dispute settlement procedures.\textsuperscript{29} TRIPs differs from previous attempts at agreements regulating international intellectual property and trade by requiring member nations to provide domestic procedures and remedies to help enforce the rights of patentees.\textsuperscript{30}

\textbf{a. Extent of Patent Rights Under TRIPs}

The TRIPs agreement is one of about twenty five legal agreements establishing the WTO, and the only one which covers IP rights specifically.\textsuperscript{31} The Agreement establishes an international minimum standard for intellectual property protection, and as such, grants individual member nations great control over their domestic laws. However, deference is afforded so long as the laws are in compliance with TRIPs.\textsuperscript{32} The minimal standard of protection for patents under TRIPs was not arrived at easily as a huge gap exists between the intellectual property goals of developed and least developed / developing

\begin{flushright}
\footnotesize
\textsuperscript{25} See Understanding the World Trade Organization, Uruguay Round Agreements, at http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact5_e.htm (last visited Apr. 15, 2004). (This link provides general information about the Uruguay Round Agreements.).
\end{flushright}

\begin{flushright}
\textsuperscript{26} Id.
\end{flushright}

\begin{flushright}
\textsuperscript{27} Id.
\end{flushright}

\begin{flushright}
\end{flushright}

\begin{flushright}
\textsuperscript{29} Id.
\end{flushright}

\begin{flushright}
\end{flushright}

\begin{flushright}
\textsuperscript{31} World Trade Organization, \textit{supra} note 25.
\end{flushright}

\begin{flushright}
\textsuperscript{32} GEORGE R. STEWART, MYRA J. TAWFIK AND MAUREEN IRISH, \textit{INTERNATIONAL TRADE AND INTELLECTUAL PROPERTY: THE SEARCH FOR A BALANCED SYSTEM} 100 (WESTVIEW PRESS 1994).
\end{flushright}
Moreover, the TRIPs agreement was more than the result of negotiations debating the economic needs of the member nations, it also represented a balance between the humanitarian needs of the developing and least developed countries and the legal rights of the developed countries (most major patent holders reside in developed countries). The least developed and developing countries did not want strong patent protection as it drastically increases the cost of importing patented products for sale in their countries. Before TRIPs, many of the least developing or developed countries refused to grant patent rights to several types of products. Brazil, for example, refused to grant patent rights to pharmaceuticals prior to 1996 even though they are the fourth largest market for pharmaceuticals in the world. In fact, the United States refused to recognize many types of patents when it was a young emerging nation. The motivation for less IP protection is simple economics for developing nations: denying patent protection increases competition thereby reducing price.

33 Id at 166.
34 Id.
35 Id at 167. (Loose patent protection laws have positive short term effects for least developed or developing nations as not only does it cost significantly more to import patented versions of drugs than their generic counterparts, but the companies who produce the medicines do not reside in their borders (no short term net economic loss). However, loose patent laws have been proven to injure the economies of these countries in the long term. IP rights in developing countries must be strong otherwise, the benefits of technology and exploitation of technological advancement will not be available in the developing economies; instead it would simply flow back to the foreign patent holder. Strong patent protection combined with the generally cheap labor in poorer countries, encourage companies to invest in manufacturing technology which eventually lead to research and development of new domestic patents. Strong patent protection also promotes foreign investment by affording foreign patentees an opportunity to issue licenses to manufacture or distribute the patented product domestically. These licenses are made with domestic companies, who are able to enjoy some of the profits from the patent, thereby strengthening the economy.).
36 Peng Jiang, Fighting the AIDS Epidemic: China’s Options Under The WTO TRIPS Agreement. 13 ALB. L.J. SCI. AND TECH. 223, 225 (2002). (At the beginning of the Uruguay Round table Trade Negotiations, more than fifty nations did not offer patent protection on pharmaceuticals.).
THE JOURNAL OF INTERNATIONAL BUSINESS & LAW

i. Source of Patent Rights: Article 28 of TRIPs

Article 28 enumerates an inventors patent rights under TRIPs. This article mandates that the patent owner has the right "to prevent unauthorized persons from using the patented process and [from] making, using, offering for sale, or importing the patented product or a product obtained directly by the patented process." The right of a patent holder to exclude others from practicing his invention is one of the most basic of all rights afforded to inventors. Often referred to as a negative right, the exclusion of others grants the patent owner a monopoly as an incentive to make the initial investment in development and as a reward for creativity which ultimately benefits the public. However, the minimal standard of protection afforded under Article 28 leaves member nations with great flexibility with regard to their domestic intellectual property laws.

b. Exceptions to Patent Rights Under TRIPs

Even though the TRIPs agreement creates a minimum standard for intellectual property rights, the drafters created several "exceptions" member nations may rely upon in certain circumstances. The Agreement contains provisions allowing for compulsory licensing under Article 31, exclusion of patent protection under Article 27, parallel importing under Article 6, and adopting measures necessary to promote the public health under Article 8.41

i. Patentable Subject Matter: Article 27 of the TRIPs Agreement

Article 27(2) of TRIPs permits the government of a member nation to "exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect "ordre public" or morality, including to protect human, animal or plant life or health or to avoid

---

38 Agreement on Trade Related Aspects of Intellectual Property Rights, April 15, 1994, art. 28
states:

1. A patent shall confer on its owner the following exclusive rights:
   (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;
   (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.
2. Patent owner shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

39 Id. art. 28(1)(b).
40 ALAN S. GUTTERMAN AND BENTLEY J. ANDERSON, INTELLECTUAL PROPERTY IN GLOBAL MARKETS (KLUWER LAW 1997). (A survey of the intellectual property laws of most countries as well as the TRIPs agreement show that the negative right granted to patentees is common throughout.).
41 Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1994, art. 8, 27(2), & 31.

227
serious prejudice to the environment. In other words, a member nation may deny patentability to a single or class of inventions if that government determines the invention’s introduction into the domestic market would have one of the aforementioned ill effects. However, Article 27(2) does not act as a “free for all” provision. Instead, it sets a high threshold before it is applicable and then, only for a limited time.

A disturbance of “ordre public” is much more than mere public order or public interest. The concept of “ordre public” stems from security concerns, such as riots, widespread public disorder, or inventions which might lead to criminal or other behavior the government finds generally unacceptable. The “ordre public” provision is quite broad, and includes “protecting human, animal or plant life or health.” Unfortunately, the agreement is silent about what constitutes a danger to any of the categories enumerated in Article 27(2), leaving this decision up to the individual member nations.

The concept of morality with respect to patentability is equally vague. Morality differs drastically from generation to generation and is almost entirely subject to the whim of the values prevailing in society at that point. TRIPs leaves the definition of morality up to the individual governments of the member nations because, it is believed, they are best able to determine what constitutes morality for themselves.

Before Article 27(2) is invoked by a member nation, two restrictions must first be met. First, patent rights may only be denied if the commercial exploitation of the invention would injure the interests enumerated in Article 27(2); requiring more than a mere determination of danger from a patented product. It follows logically that if a product is too dangerous to be afforded patent protection under Article 27(2) — a threat to “ordre public” — it is too dangerous to be imported. Thus, accompanying legislation is almost always required when Article 27(2) is invoked and this exception rarely serves to sidestep legal rights in favor of cheaper products.

42 Id. art. 27(2).
43 Peng Jiang, Fighting the AIDS Epidemic: China’s Options Under The WTO TRIPs Agreement. 13 ALB. L.J. SCI. AND TECH. 223, 230 (2002). (A member nation which excludes a product from patent protection can only do so for as long as the emergency situation continues. After that, protection must be restored.)
45 Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1994, art. 27(2).
46 Peng Jiang, Fighting the AIDS Epidemic: China’s Options Under The WTO TRIPs Agreement. 13 ALB. L.J. SCI. AND TECH. 223, 229 (2002). (In fact, there is currently a debate over the exact breadth of this provision. Least developed countries argue that the provision allows a country to loosen patent protection for certain medicines because this protects the “ordre public.” The other side claims that the plain meaning of the provision must be understood to explain that the patentability of harmful inventions is not protected; which is wholly separate to the patentability of merely expensive ones.).
47 id. id.
Second, under Article 27(2), exclusion from patentability is not allowed if the reasoning is merely because of a conflict with existing domestic law. In other words, the basis behind the exclusion must come from the Article itself, not from domestic law. 49

ii. Principles: Article 8 of the TRIPs Agreement

Article 8 of the TRIPs agreement is also built on the theory that in certain circumstances, the public good must outweigh the inventors rights. 50 Almost as soon as it was enacted, Article 8 was used by member nations as a major road around the patented protection of certain products. 51 This article allows members to formulate, amend or “adopt measures necessary to protect public heath and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.” 52

Article 8 of TRIPs reflects the sovereign power of nations to protect the welfare of their citizens. This article, simply put, allows member nations to enact legislation beyond the extent of TRIPs. The only requirement a government must meet is that the measures or legislation adopted is “necessary to protect public health.” 53 As is consistent within TRIPs, determinations like morality, dangers to “ordre public” and necessity are left in the hands of the individual member nations.

Several countries have used Article 8’s regulatory exception to legalize parallel imports, compulsory licenses, and generic drugs in an attempt to ease the suffering of a public health crisis. 54 Domestic legislation enacted under Article 8 was recently upheld by the WTO dispute resolution body which held

49 Id.
52 Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1994, art. 8 states: (1) “Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

(2) Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.”
53 Id. (Emphasis added).
that Canadian law legalizing compulsory licensing, parallel importing and
generic drugs was in conformity with TRIPs.  

iii. Compulsory Licenses: Article 31 of TRIPs Agreement

Compulsory licenses are a feature of non-American patent law which
allows for involuntary licensing of patented products. Compulsory licenses
work as follows: Company A wants a license from company B to produce a
certain patented product. However, because company B wishes this product only
to be marketed under their trademark (or for other reasons), they refuse
company A's offer. Company A may now obtain a compulsory license
regardless of company B's express desire not to issue one. The license cost is
calculated differently depending upon the laws of the nation in which the
companies reside. Most governments have traditionally been compulsory license
friendly because they greatly increase competition and thereby reduce costs.
Compulsory licenses have been shown to reduce the cost of certain
pharmaceuticals by as much as ninety-five percent. Article 31 of TRIPs
encompasses "other use without authorization of the right holder" – a.k.a.
compulsory licensing.

Compulsory licensing is permitted under Article 31 of the TRIPs
Agreement "where the law of a Member allows for other use of the subject
matter of a patent without the authorization of the right holder, including use by
government or third parties authorized by the government." TRIPs, however,

55 WTO Panel Decision WT/DS114/R, available at
http://www.wto.org/english/tratop_e/dispu_e/distabase_wto_members1_e.htm (last visited Apr. 15,
2004). (Decision made March 17th, 2000. Choose the link for Canada as respondent and search for
WT/DS114/R).
56 WILLIAM H. FRANCIS & ROBERT C. COLLINS, CASES AND MATERIAL ON PATENT LAW 772 (5th
context governed by TRIPs. Legal scholars in the United States consider compulsory licenses to be
contrary to one's freedom to contract as well as the basic right of exclusion granted to patentees.).
57 Rosalyn S. Park, The International Drug Industry: What the Future Holds for South Africa's
58 Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1994, art. 31(a) and
(b), state:

Where the law of a Member allows for other use of the subject matter of a patent without
the authorization of the right holder, including use by government or third parties
authorized by the government, the following provisions shall be respected:

(a) authorization of such shall be considered on its individual merits;
(b) such use may only be permitted if, prior to such use, the proposed user has made
efforts to obtain authorization from the right holder on reasonable commercial terms and
conditions and that such efforts have not been successful within a reasonable period of
time. This requirement may be waived by a Member in the case of a national emergency
or other circumstances of extreme urgency or in cases of public non-commercial use. In
situations of national emergency or other circumstances of extreme urgency, the right
holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of
public non-commercial use, where the government has demonstrable grounds to know
that a valid patent is or will be used by or for the government, the right holder shall be
informed promptly;

59 Id.
does not allow a government to grant compulsory licenses in all cases. Article 31 subjects the government of the member nation to several conditions before a compulsory license may be granted. The first, and most basic condition is that only the government of a member nation may grant compulsory licenses.60

Article 31(b) provides that compulsory licenses are proper only when [1] "the proposed user has made efforts to obtain authorization from the patent holder on reasonable commercial terms" and [2] "that such efforts have been unsuccessful within a reasonable period of time."61 However, the good faith effort requirements of Article 31(b) can be waived in a time of "national emergency, in circumstances of extreme urgency, or in cases of public non-commercial use."62 In other words, Article 31(b) of TRIPs forces governments to negotiate in good faith for a reasonable period of time, but leaves open a loophole to be used only when some catastrophe has made time extremely scarce.

Another controversial aspect of Article 31 is subsection (f) which requires the compulsory license to be "authorized predominately for the supply of the domestic market of the Member state authorizing such use."63 It is not entirely clear whether Article 31(f) requires countries to manufacture the product domestically, or whether they may have a foreign third party manufacture the product to be imported. The opponents of the latter interpretation argue that the third party is not privy to the circumstances giving rise to the compulsory license and, therefore, should not be allowed to manufacture the patented product. As of 2004, this dilemma has not been resolved.

Although Article 31 clearly grants a member nation the right to grant compulsory licenses at times of "national emergency or extreme urgency," the Agreement itself gives no standards by which to define these terms.64 Another problem is that Article 31(h) provides: the "right holder shall be paid adequate remuneration" for the license.65 Again, the Agreement provides no standards by which to define "adequate remuneration."66 Typically, in domestic affairs, reasonable royalties have been calculated based on what the patentee has offered similarly situated licensees in the past, but this is an imperfect rule as costs and

---

61 Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1994, art. 31(b).
62 Id.
63 Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1994, art. 31(f), states: (f) any such use shall be authorized predominately for the supply of the domestic market of the Member authorizing such use;
65 Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1994, art. 31(h), states: (b) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.
66 Id.
complications can increase the price dramatically when dealing with overseas exports.\textsuperscript{67}

iv. Parallel Importation: Article 6 of TRIPs Agreement

Parallel importation is another method used to reduce patented drug prices. Parallel importation occurs when an original licensed purchaser buys the patented product, then sells it to a third non-licensed party (without permission from the patentee).\textsuperscript{68} This type of trade occurs because pharmaceutical companies will tier their prices depending on the individual member nation. For example, a particular drug will be sold to Country A for $X, and Country B for less than $X. Under this method, Country A would sell their patented product to Country B, instead of B buying directly from the pharmaceutical company.\textsuperscript{69} Parallel importation stems from the patent law concept of exhaustion.\textsuperscript{70} This theory holds that once a patented product is sold (placed in the stream of commerce) its subsequent resale is no longer determined by the patentee — in other words, his rights to that product are exhausted.\textsuperscript{71}

The TRIPs Agreement addressed this issue by refusing to take a position.\textsuperscript{72} Article 6 of the TRIPs agreement states: “For the purposes of dispute settlement under this Agreement, subject to the provisions of Article 3 and 4 nothing in this Agreement shall be used to address the issue of exhaustion of intellectual property rights.”\textsuperscript{73} Thus, Article 6 of TRIPs manifests the drafters intention to leave the issue of parallel importation up to the individual Member States. Due to the position TRIPs adopts in Article 6, the question still remains whether a patent holder’s rights are exhausted globally once a product is sold anywhere in the world.

Parallel importation acts as a double edged sword, however, because while it can reduce the prices of pharmaceuticals for a single nation, it will at the same time force the manufacturers to raise prices globally to counteract their lost profits. This is a highly contested issue as parallel importation on a global scale would allow an American to buy pharmaceuticals at the price offered in Brazil. Although, for the American buyer, this seems ideal, it actually serves to defeat the goals of TRIPs because this forces Member Nations to restrict trade to keep prices up. Although parallel importation is a hotly contested issue, it is one with which TRIPs can offer no assistance. The drafters choose to remain silent regarding this issue, which now forces the member nations to determine this for themselves.

\textsuperscript{69} Id. (This note supplies a good example of parallel importing: Fluconazole (Diflucan) bought directly from a patent holding company costs $4.10 per dosage. This drug could be purchased through parallel importation from Thailand for $0.60 per dosage.).
\textsuperscript{70} Id.
\textsuperscript{71} Id.
\textsuperscript{72} Agreement on Trade Related Aspects of Intellectual Property Rights, April 15, 1994, art. 31(h).
\textsuperscript{73} See Id at art. 6.
IV. THE SOUTH AFRICAN MEDICINES AND RELATED SUBSTANCES ACT OF 1997

As previously stated, South Africa is currently suffering from an HIV/AIDS epidemic of almost biblical proportions. Unfortunately, the population of South Africa is very poor and cannot afford the proper medication. In response to the public outcry, the Parliament of South Africa enacted the South African Medicines and Related Substances Act of 1997 (SAMRSA), and its subsequent Medicines and Related Substances Amendment Act of 2002, which empowered the Minister of Health to make broad decisions concerning the intellectual property laws of the country. The SAMRSA was drafted to help increase "the supply of more affordable medicines and to protect the health of the public." However, despite the Act’s seemingly noble goals, it was met with great resistance from the international community, mainly the United States. The developed countries saw the SAMRSA as the beginning of the end for pharmaceutical patent rights and argued that the Act violated the TRIPs agreement. In particular, two provisions of SAMRSA were argued to be in violation of TRIPs - §§15(c) and 22(c). These provisions are examined below.

a. SAMRSA §15(C): Powers of the Minister of Health

Opponents of SAMRSA argue that §15(C) grants the South African Minister of Health very broad powers relating to patent rights in South Africa. The first provision, §15(C)(a), prescribes that the Minister of Health may truncate the patent holder’s rights of a medicine already placed into the South African market, such that his rights do not extend to “acts” regarding the patented medicine. This provision makes a distinction between the patent holder’s rights to the patented product and his rights to control that medicine once entered into the South African marketplace. However, SAMRSA does not provide a definition of “acts,” nor does it elaborate on when the Minister of Health may limit a patent holder’s rights.

Section 15(C)(b) of SAMRSA is probably the most controversial provision in the Act because it pertains to both compulsory licensing and the importation of generic versions of patented medicines. In addition, the language chosen to achieve this goal is arguably broad. Section 15(C)(b) grants the
Minister power to “prescribe the conditions for importation of a medicine which is: [1] identical in composition; [2] meets the same quality standards; [3] has the same name as that of another medicine already registered in South Africa; [but, 4] which is imported by someone other than the holder of the original registration certificate; and [5] which originates from any site of manufacture.”

It fails to address other qualifications for compulsory licenses outlined in Article 31 of TRIPs such as adequate compensation, or good faith negotiations.

Section 15(C)(c) of SAMRSA gives the Minister power to determine the registration procedure and subsequent domestic “use of” any medicine referred to in §15(C)(b). The fact that this section grants power to determine registration procedures and requirements is not, in and of itself, challenged. The controversial portion is the part of this section which allows the Minister to prescribe the “use of” the medicines referred to in §15(C)(b). It is unclear from the language of §15(C)(c) the extent of control over “use” the government reserves.

b. SAMRSA §22(C): Manufacture, Sale and Distribution

Section §22(C)(b) of SAMRSA, which was later amended by the South African Medicines and Related Substances Act of 2002, grants the Council power to issue a license to manufacture, sell, import, export or distribute medicines or medical devices. This provision does not contain language requiring a manufacturer, wholesaler or distributor to be domestic. Nor does it require that the products manufactured or sold under this section remain in South Africa. In fact, §22(C)(b) does not address the location of these entities.

---

82 See generally South African Medicines Amendment Act of 1997, §15(C)(b), supra note 8, states:
The minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may—
(b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported:

83 Id.
84 Id. §15(C)(c), states:
(c) prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b).

85 Id.
86 See South African Medicines and Related Substances Act of 2002, §22(C)(b), states:
(b) the council may, on application in the prescribed manner and on payment of the prescribed fee issue to a manufacturer, wholesaler or distributor of a medicine or medical device a license to manufacture, import or export, act as a wholesaler of or distribute, as the case may be, such medicine or medical device, upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the council may determine.

87 Id.
88 Id.
89 Id.
V. SAMRSA: PROBLEMS OF VAGUENESS AND COMPLIANCE WITH TRIPS

Complaints about SAMRSA can generally be broken down into two categories: vagueness and compliance. The vagueness category includes language from SAMRSA which does not clearly define legal rights and obligations. The problem with a vague law is that it creates uncertainty for those affected by it. For example, a foreign patent holder may withhold selling his patented product in South Africa because he is unsure whether that product will be granted protection. Alternatively, a patent owner could have already begun selling his product assuming he has protection, only to have that protection later retracted by the Minister of Health. The compliance category of complaints regarding SAMRSA involves language from the act which may be in violation of an article of the TRIPs agreement.

a. Vagueness Concerns

Sections 15(C)(a) and (c) both contain vague language which may result in the aforementioned legal uncertainty. Specifically, §15(C)(a) states that the Minister of Health may limit the “acts” regarding a patented medicine after that medicine has been placed in the South African market. The word “acts” is left undefined and leaves the reader questioning both what actions are included and the extent of control the Minister may assert.

Section 15(C)(c) grants the Minister of Health power to determine the “use of” a patented product in South Africa. Again, the Act fails to define the scope of the term “use of,” which, conceivably could mean anything from how the medicine is proscribed to distributed or sold. Both §§15(C)(a) and (c) have the possible result of severely limiting a patent holder’s rights with regard to his product. They also create concerns in developing nations because the extent of this limiting effect is undefined.

However, the concerns over vagueness are secondary to that of compliance. Compliance concerns are different because they raise questions on whether sections of the SAMRSA could be in violation of an international agreement; possibly rendering these sections illegal and unenforceable. These concerns are paramount because non-compliance reduces the power of the
international agreement and creates precedent that the agreement is only a paper tiger.

b. Compliance Concerns

Sections 15(C)(b) and 22(C)(b) are the focus of international concern from developed countries. These sections grant the Minister of Health broad powers concerning compulsory licenses and, the developed countries argue, these broad powers fail to comport with the minimum standards set forth in the TRIPs agreement. The first concern is that §15(C)(b) fails to prescribe conditions for granting a compulsory license such as compensation to the patent holder and good faith negotiations. The problem here is that both compensation and negotiations are requirements for a compulsory license under TRIPs Article 31(b).

The question then becomes whether the SAMRSA’s absence of the conditions established under TRIPs Article 31(b) is a violation of the minimum standard of protection offered under TRIPs. It is the opinion of this author that such absence is a violation of TRIPs. TRIPs was drafted to create a base or ground level of protection for intellectual property – an agreed minimum arrived at after extensive negotiations. A Member Nation is then free to establish any laws which supplement the minimum standards established in TRIPs, but they cannot choose to go below those minimums. For example, South Africa could have required a judge to determine the adequate compensation for patent holders in compulsory license cases. This would represent a standard greater than that required by TRIPs Article 31. The SAMRSA, however, wrote into law requirements that are lower than is written in Article 31 – thereby violating the TRIPs agreement.

Another concern over §15(C)(b) is the principle of territoriality which prevents one Member Nation from interfering with the rights of a patent owner in another Member Nation. It is argued that the principle of territoriality is found in TRIPs under Article 31(f) which precludes a Member Nation from getting a compulsory license and then having the goods manufactured in another country. Article 31(f) of TRIPs states that “any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.” The language “predominantly for the supply of the domestic market” gives rise to the principle of territoriality.

---

95 See Notice of Motion in pharmaceutical case, supra note 79.
96 Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1994, art. 31(b). (See note 58 supra for the entire article.).
98 Id at 1334. (Member Nations with poor manufacturing capabilities cannot get compulsory licenses if that country cannot manufacture the product domestically due to the principle of territoriality.).
99 Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1994, art. 31(f).
100 See Divya Murthy, supra note 97.
Section 15(C)(b) of SAMRSA states that the South African government may prescribe conditions for which a medicine meeting certain standards and manufactured by one other than the patent holder "may be imported." The contested part of this section is not that it gives the South African government the power to issue compulsory licenses; rather, it is that §15(C)(b) gives the government the power to issue compulsory licenses to foreign nations, which violates the principle of territoriality created under Article 31(f) of TRIPs. For example, South Africa could grant a domestic company a compulsory license for medicines which would be manufactured out of country. The problem with this manufacturing arrangement is that the compulsory license would be for South Africa only— not the third party foreign manufacturer, and now that third party would be receiving an unjust enrichment because they also benefit from the lower prices brought by compulsory licenses.

Section 22(C)(b) of SAMRSA and its related Amendment Act in 2002, present similar problems with territoriality. This section can be read to be in violation of Article 31 of TRIPs under two different interpretations. First, §22(C)(b) seems to allow for importation of foreign manufactured patented products under a compulsory license granted to South Africa. Second, §22(C)(b) allows for exportation of a product manufactured in South Africa under a compulsory license granted to that country only. Both of these situations violate the principle of territoriality because they allow foreign third parties to be included in a compulsory license, which by the terms of Article 31(f), should only be granted for predominately domestic purposes.

However, it is argued by certain legal scholars that territoriality is a changing concept and may no longer be a bar when a developing or least developed country lacks the capability to manufacture medicines domestically. This argument is based on changing world trade relations and the immediacy of the AIDS epidemic. Thus, it depends on whether the WTO considers territoriality to be part of TRIPs or a fleeting concept no longer alive in international trade law—a decision which has not been decisively resolved.

VI. IS THE SAMRSA REALLY NECESSARY?—SOLUTIONS WITHIN TRIPS.

South Africa’s goal to get affordable medication is not impossible, regardless of the SAMRSA’s debated compliance with TRIPs. The solution to
their problem can be found within several articles of the TRIPs agreement itself; most notably Article 31. TRIPs, again, represents only a minimum level of protection for intellectual property. South Africa has plenty of legal maneuvering room within this agreement such that it need look no further to solve the countries patent woes.

a. Article 31(b) – National Emergency

Article 31 of the TRIPs Agreement grants all Member Nations the power to issue compulsory licenses in certain circumstances. Under this article, South Africa may act in one of three ways. First they may negotiate with the pharmaceutical companies for authorization from the patent holder for a license. Unfortunately, due to their complex nature, and the great amount of money involved, these negotiations will probably carry very high transaction costs. If these negotiations do not succeed within a reasonable amount of time, then South Africa would be within its rights, under Article 31(b), to grant a compulsory license for the patented product so long as they give “adequate” compensation to the patent holder.

Alternatively, South Africa may bypass the negotiations entirely and grant a compulsory license for medication under Article 31(b)’s provision for situations of “national emergency or other circumstances of extreme urgency.” The question here, is whether the AIDS epidemic currently facing South Africa qualifies as a national emergency or a circumstance of extreme urgency. As is usual within TRIPs, neither of these terms are defined within the document, which gives the individual member nations the power to define them. Before South Africa chooses to invoke Article 31(b) of trips, several questions must be answered: (1) Can the AIDS epidemic be viewed as a national emergency; (2) what is required for South Africa to declare a national emergency; (3) how long can a state of national emergency be upheld; and (4) does a compulsory license granted under a state of emergency prohibit future good faith negotiations?

i. Is South Africa’s AIDS Epidemic a National Emergency?

In November 2001, the Council for Trade Related Aspects of Intellectual Property Rights met in Doha and agreed on how certain articles in TRIPs should be interpreted. The Doha Declaration confirmed that “each

---

108 See supra note 72 at art. 31.
109 See supra note 72 at art. 31(b).
110 Id. (Note the term “adequate” is not defined within TRIPs.) See supra note 65.
111 Id.
112 Id.
113 WTO Ministerial Conference, Declaration on the TRIPs Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 14, 2001) [hereinafter Doha], also available at http://www.wto.org/english/tratop_e/summit_e/min_01_e/min01_e/minconf_e.htm (last visited Apr. 15, 2004).
WTO member has the right to grant compulsory licenses and the freedom to
determine the grounds upon which such licenses are granted, while respecting
the terms and conditions of Article 31 of the TRIPs agreement."114 The Doha
Council also made clear that each Member Nation may determine for
themselves when to declare a national emergency for purposes of Article
31(b).115 Finally, the Declaration specifically recognized that the HIV/AIDS
epidemic "can represent a national emergency or other circumstance of extreme
urgency."116 In light of the Doha Declaration, the South African government is
within their rights under TRIPs to declare the current HIV epidemic a national
emergency. It is now important to determine if any domestic law would preclude
South Africa from declaring a state of national emergency and begin
manufacturing medicines domestically to meet the needs of their people.

ii. Declaring a National Emergency

South Africa, in light of the Doha Declaration, has complete control
over its national state of emergency for purposes of Article 31(b). Unfortunately,
South Africa’s domestic law pertaining to such a declaration is not as clear.
Section 34 of the South African Constitution holds: “A state of emergency shall
be proclaimed prospectively under an Act of Parliament, and shall be declared
only where the security of the Republic is threatened by war, invasion, general
insurrection or disorder or at a time of national disaster, and if declaration of a
state of emergency is necessary to restore peace and order.”117

Although none of the above language directly relates to disease, South
Africa can still rely on the language of section 34 in declaring a state of
emergency. South Africa can argue that their current HIV epidemic represents a
“national disaster.”118 HIV could easily be viewed as a national disaster since
one in five adults are believed to be infected;119 South Africa’s national
economy continues to shrink by 1% each year due to a sick workforce;120 life
expectancy in South Africa is expected to drop from 70 to 50 years by 2010;121 and
there are an estimated 1,600 new infections daily in South Africa.122
Furthermore, it is estimated that between 140 and 150 thousand deaths occurred
in 2000 alone due to AIDS related complications.123 This last statistic dwarfs by

114 Id.
115 Id.
116 Id.
117 Patrick Marc, Compulsory Licensing and the South African Medicine Act of 1997: Violation or
Compliance of the Trade Related Aspects of Intellectual Property Rights Agreement?, New York Law
118 Id.
119 Gumisai Mutume, supra note 1.
120 Bombach, supra note 13, at 283.
121 Id.
122 South Africa Scales Down Population Estimate with 300,000 due to AIDS, at
Apr. 15, 2004).
comparison the deaths caused in Iran's 2003 earthquake in which 40,000 people tragically died.\textsuperscript{124} Since the HIV virus is a product of nature, and due to the virus' effect on the economy, and the exorbitant toll on life, South Africa would be within its rights under §34 of the South African Constitution to declare a state of national emergency based upon this national disaster.

iii. Duration of a National Emergency

Since there is currently no cure for HIV/AIDS, the best medication can only help the patient live with the disease by minimizing the problems related to immune deficiency. Therefore, South Africa would have to declare a state of national emergency for a minimum of decades so that their population can continue to benefit from the lower prices brought by a license. A long term solution is critical. If the flow of affordable or free medication were to stop, then South Africa would greatly complicate their problem by creating a medicine resistant strain of HIV.

TRIPs Article 31(g) states that a compulsory license shall terminate "if and when the circumstances which lead to it cease to exist and are unlikely to recur."\textsuperscript{125} Keeping with this language, it can be argued that so long as South Africa continues to suffer from over one hundred thousand AIDS related deaths annually, a state of national emergency could continue to exist. Typically, however, nations do not declare a state of national emergency for decades, and as mentioned above, those infected with the HIV virus must continue to take medication for their entire lives. Therefore, although South Africa can declare a state of national emergency, this is only a temporary solution as they will lose the compulsory license when they eventually return to a non-emergency state.


South Africa must also examine whether a compulsory license which was originally created under a state of national emergency can be transferred into one based on good faith negotiations. In other words, can South Africa declare a state of national emergency, get a compulsory license with minimal delay, and then negotiate with the pharmaceutical manufacturers? The obvious benefit of this approach is that South Africa could eliminate public pressure from their people while lengthy negotiations are underway.

Critics of such a tactic will argue that it violates Article 31(b)'s requirement of good faith negotiations. This, however, is not the case. Article 31(b) still requires a member nation to declare a state of national emergency before a compulsory license can be granted without prior negotiations. It is highly unlikely that countries will begin scaring their population and confusing the rest of the world by declaring false states of emergency only to lower

---


\textsuperscript{125} Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1994, art. 31(g).
transaction costs. Therefore, since nothing in TRIPs Article 31 prohibits good faith negotiations after a license was granted based on a country declaring a national emergency, South Africa should not fear long term problems from this interim solution.

b. Article 31(b): Public Non-Commercial Use

A third way South Africa may exploit Article 31(b) to their advantage is to restrict the manufacturing of medicines to "public non-commercial use."\(^{126}\) In order to invoke this provision, South Africa would have to create non-profit government owned pharmaceutical manufacturing plants. The sole purpose of the plants would be providing medication for their domestic population. Article 31(b) clearly states that such a use would be in compliance with the TRIPS Agreement.

This provision probably represents South Africa's best option for providing affordable medication for their public under the TRIPS Agreement because it creates a long term solution. If South Africa were to create government owned, hence public, non-commercial manufacturing facilities, it could then grant compulsory licenses for HIV medication and distribute that medication to the public at almost no cost to the user. While, this plan would require the South African government to bear almost all of the cost of manufacturing the medicines, this cost would be offset by the increased productivity of a healthy workforce and the lower cost of producing the medication due to the compulsory license granted under this provision.

It is important to note that the Doha Declaration held that the TRIPS Agreement is intended to be read favoring pro-health policies of member nations. For example, the Declaration states: "the TRIPS Agreement does not and should not prevent members from taking measures to protect public health."\(^{127}\) Furthermore, the Declaration continues: "the [TRIPs] Agreement can and should be interpreted and implemented in a manner supportive of WTO member's right to protect public health and, in particular, to promote access to medicines for all."\(^{128}\) In light of this language, South Africa should not fear a grievance brought before the WTO Dispute Settlement Body if they were to invoke this section of Article 31(b) and begin manufacturing medication domestically for non-commercial use.

c. Other Options Under TRIPs

i. Article 6: Parallel Importation

Article 6 of TRIPs also gives South Africa options for cheaper medication. This article states that "nothing in this Agreement shall be used to
address the issue of exhaustion of intellectual property rights” – namely parallel imports.\textsuperscript{129} Furthermore, the Doha Declaration confirmed that “each Member Nation is free to establish its own regime of exhaustion of intellectual property rights without there being a challenge in the WTO dispute settlement system.”\textsuperscript{130} Therefore, the TRIPs Agreement read in light of the Doha Declaration gives South Africa the power to import medication from a parallel source, thereby lowering drug prices and meeting the needs of their people.

This solution, however, is not without its problems. Pharmaceutical manufacturers will quickly adapt the current pricing tiers to account for parallel importation if it becomes too prevalent. In other words, the situation may arise where a certain drug is cheapest in Country C, and in response, Countries A and B (where due to pricing tiers, the medication is more expensive than in Country C) refuse to buy directly from the manufacturer, buying instead entirely from Country C.\textsuperscript{131} In the long run, this type of arrangement will only force the pharmaceutical manufacturers to increase prices globally or restrict the volume of medicine sent to any one country (perhaps based on need). Although parallel importation is a quick fix, it creates problems when used as a permanent solution and should only be used to supplement the supply of medicine, not create it.

\textbf{ii. Article 8: Adopting Complaint Domestic Law}

Finally, Article 8 of the TRIPs agreement grants Member Nations the right to “adopt measures necessary to protect public health.”\textsuperscript{132} Article 8 gives all Member Nations the right to create domestic legislation to handle their country specific intellectual property issues. South Africa relied on this Article in adopting the SAMRSA and could do so again, if they opted to further amend their SAMRSA so is it in compliance the TRIPs agreement.

Brazil is a great example of a country which used Article 8 to their advantage. Prior to 1996, Brazilian law granted no patent protection for pharmaceuticals.\textsuperscript{133} Upon joining the WTO, however, Brazil had to change their law to comply with TRIPs. Brazil reworked their domestic patent law to meet the minimum requirements under TRIPs, but created a loophole for pharmaceuticals under Article 8. Under modern Brazilian law, a drug is patentable “only if the product has not been marketed anywhere and if no serious and effective preparations for exploitation of the corresponding product have been carried out by third parties in Brazil.”\textsuperscript{134} This provision has the effect of denying patent protection to all HIV medication which was commercialized anywhere in the world prior to May 14, 1997.\textsuperscript{135} Due to the intelligent drafting

\begin{flushright}
\textsuperscript{129} Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1994, art. 6
\textsuperscript{130} Doha, \textit{supra} note 113.
\textsuperscript{131} Eppich, \textit{supra} note 28, at 293. (For example, a 500 mg tablet of Cipro sells for $4.67 in the United States, $1.29 in New Zealand, and $2.10 in South Africa.).
\textsuperscript{132} Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1994, art. 8
\textsuperscript{133} Jiang, \textit{supra} note 30, at 238.
\textsuperscript{134} \textit{Id.}
\textsuperscript{135} \textit{Id.}
\end{flushright}
of their intellectual property laws, Brazil was able to force prices of patented drugs competing in their market down 79%. This also had the positive effect of reducing the death rate due to AIDS by 50%.

VII. CONCLUSION

No one can deny the crisis facing South Africa. South Africa's population is too poor to afford the high prices of patented medication and this situation is causing death at an alarming rate. Fortunately, there are solutions to this problem. South Africa can create domestic law similar to that enacted by Brazil under Article 8. This new law would, of course, have to be in compliance with the minimum standards of the TRIPs agreement, but, the agreement leaves member nations wide latitude to meet their individual needs.

South Africa could also create a compulsory license for the medication under Article 31 of TRIPs. This license can be granted in one of three ways. First, South Africa can negotiate with the pharmaceutical manufacturers directly. Second, South Africa can declare a state of national emergency relying on the “national disaster” provision of §34 of their Constitution. Third, South Africa can invoke the “public non-commercial use” provision of Article 31(b) and grant a compulsory license to government owned domestic pharmaceutical manufacturers.

Finally, South Africa can supplement their own supply of medication through parallel imports under Article 6 of the TRIPs Agreement. It is important for South Africa, as well as the developed countries of the world to remember that the TRIPs Agreement was created to provide a minimum standard of protection for intellectual property. Furthermore, this Agreement, as clarified by the Doha Declaration, is intended to “...be interpreted and implemented in a manner supportive of WTO member’s right to protect public health and, in particular, to promote access to medicines for all.”

136 Id.
137 Id.
138 Doha, supra note 113.
THE STARR FOUNDATION

The Starr Foundation was established in 1955 by Cornelius Vander Starr, an insurance entrepreneur who founded the American International family of insurance and financial services companies, now known as American International Group, Inc. (NYSE:AIG). Mr. Starr, a pioneer of globalization, set up his first insurance venture in Shanghai in 1919. He died in 1968 at the age of 76, leaving his estate to the Foundation.

The Foundation currently has assets of approximately $3 billion, making it one of the largest private foundations in the United States. It makes grants in a number of areas, including education, medicine and healthcare, public policy, human needs, culture and the environment.

In addition to endowed C.V. Starr Scholarships, the Foundation also supports financial aid programs and specialized internships at numerous undergraduate and graduate institutions nationwide, including schools of law, business, technology and liberal arts, as well as the United Negro Scholarship Fund and a group of historically black colleges and universities.