Examining Global Access to Essential Pharmaceuticals in the Face of Patent Protection Rights: The South African Example

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EXAMINING GLOBAL ACCESS TO ESSENTIAL PHARMACEUTICALS IN THE FACE OF PATENT PROTECTION RIGHTS: THE SOUTH AFRICAN EXAMPLE

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The divide between world income and access to life saving medicines is great. Many poor countries try to implement policies to help their citizens acquire affordable medicines in order to close the economic gap. The HIV/AIDS pandemic creates an enormous demand for essential drugs. Moreover, the alarming HIV/AIDS related death rates in Sub Saharan Africa offers a compelling reason for urgently meeting the demands of attaining essential drugs. This article focuses on the South African example. However, the dilemma is acutely global.

OVERVIEW

The magnitude of the HIV/AIDS crisis in South Africa coupled by the difficulty of obtaining affordable and essential drugs, forced the government in 1997 to enact legislation that intended to address this critical public health crisis. The government enacted Section 15(c) of the South African Medicines and Medical Devices Regulatory Act (SAMMDRA), authorizing parallel imports and compulsory licensing with the objective of allowing easier access to affordable drugs.

PARALLEL IMPORTS AND COMPULSORY LICENSING

Parallel importing is a feature of price disparity among different countries. Countries practice parallel importing when they globally seek lower priced medicines and permit the drugs' import, rather than restrict purchases at higher priced versions of the same drugs from local distributors.1 Parallel imports are an effective means for poor and developing

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countries to achieve lower priced drugs. In addition, parallel imports benefit many European Community countries, where the government is the chief payer for health care services, including pharmaceuticals. For example in 1995, an identical amount of the antibiotic Amoxil, made by SmithKline Beecham, cost $8 in Pakistan, $14 in Canada, $36 in the United States, $40 in Indonesia and $60 in Germany. Parallel importing would lessen the pricing gap.

"Compulsory licensing" allows regular licensure grants to a third party that will manufacture a drug still under patent. The third-party licensee is able to use the patented product or process. In return, the patentee has a right to adequate royalty payments, at a rate set by the host legislature. Wider access to drugs, stimulated by economic mechanisms, aims to increase the supply for the use of AZT, taxol, protease inhibitors, and other drugs intended to counter the progression of AIDS, within South Africa.

The response to South Africa's initiative was combative. Forty major drug companies sued, countering the bold Act in an attempt to protect pharmaceutical patent rights and corporate profits. The United States added more fuel to the fire and waged an aggressive campaign to reverse the South African law.

During the fierce, two-year campaign against SAMMDRA, members of the global public health community and consumer interest groups joined forces to protest the pharmaceutical industry's efforts. As a result of the sustained pressure, the United States eventually withdrew the suit in September 1999. For its part, South Africa agreed to abide by the General Agreement on Tariffs and Trade (GATT) and the Trade-Related Intellectual Properties Rights (TRIPS) provisions in implementing subsequent drug initiatives.

However, the apparent change in the U.S. posture toward SAMMDRA 15 (c) did not eliminate the ongoing broader dilemma of balancing public health concerns and pharmaceutical patent rights. This article explores how that dilemma was manifest within the South African context. It examines how changes in political posture should further manifest into con-

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2 See Ralph Nader, Al Gore Bullies South Africa on U.S.-made AIDS drugs, KNIGHT RIDDER TRIBUNE, April 26, 1999, at Commentary.
5 LANCET JOURNAL, Mar. 3, 1999. On Compulsory drug licensing for countries hit by HIV.
crete policies. It posits that the United States Trade Commission must adopt less restrictive trade standards to other countries concerned.

This article contains four parts. Part I highlights the AIDS/HIV epidemic, with an emphasis in Africa. Part II examines South Africa’s response with its HIV/AIDS crisis through SAMMDRA and provides a discussion of the relevant legislative provisions, including a detailed review of parallel importing and compulsory licensing. Part III assesses the responses of U.S. interests by examining perspectives from the National Institutes of Health (NIH) and the pharmaceutical industries. Part IV seeks alternatives to the crises with an evaluation of the U.S. trade policy and the World Health Organization (WHO) in light of existing rules and laws under the World Trade Organization (WTO), including the Bayh-Dole Act. The paper concludes with an exploration of the advantages and disadvantages of maintaining current trade policies. It provides a discussion of alternate approaches based on the assertion that the U.S. must apply to its new pharmaceutical trade policy reform with South Africa to all countries seeking equitable and consistent trade and health policies.

I. THE GRAVITY OF THE GLOBAL AIDS/HIV EPIDEMIC

The AIDS epidemic is the critical public health challenge for most developing nations. Sub-Saharan Africa is dramatically affected. Only 10% of the world’s population reside in this region; however, it bears a staggering 70% of the world’s new AIDS cases. One in seven Kenyans and one in four Zimbabweans have HIV/AIDS. In South Africa, 22 percent of adults are HIV positive. South African life expectancy was 59 years in 1990; by 2010, life expectancy may be less than 40 years.

The Report on the Presidential Mission on Children Orphaned by AIDS reveals that deaths resulting from AIDS in sub-Saharan Africa will exceed the number of people that died in Europe during the plague of


See Weissman, supra note 3, at 40.

See id.

See id.
The U.S. Surgeon General estimated the current number of sub-Saharan Africans infected with HIV/AIDS at 22 million. Over the next ten years, AIDS will kill more people in sub-Saharan Africa than the total number of casualties in all wars of the 20th Century, each day 5,500 die in the region from AIDS-related causes.

Africa is not alone in this devastating crisis. There are 6.7 million people infected in East and Southern Asia and 1.4 million infected in Latin America. For the most part, these areas represent poor countries that cannot afford high drug prices to ameliorate the disease. The capacity of any country to treat HIV/AIDS patients relates to the level of the country’s income and the rate of infection. Consequently, most of the 30 million HIV/AIDS patients in poor countries will die with a shorter life span, from an inability to afford drugs or adequate health care services.

Top drug treatments in the United States coupled with a high standard of living enable many people with HIV/AIDS to live relatively healthy lives for an increasingly longer period. However, in much of Africa this is not the case. Most Africans with HIV/AIDS die rather quickly. HIV/AIDS-drug cocktails cost about $12,000 a year in many African countries, which represents a cost that is prohibitive for most of the growing African population with HIV/AIDS.

Accordingly, the HIV and AIDS crisis is a global public-health crisis that evokes economic demands for dramatic and swift interventions. That is why nations such as South Africa have responded by instituting policies that will stimulate and ease access to affordable essential medicines.

II. SAMMDRA: THE SOUTH AFRICAN RESPONSE TO ITS HIV/AIDS CRISIS

In 1997, at the height of the AIDS epidemic, the South African government proposed policy changes in SAMMDRA. The objectives of


See id.


See id.

Weissman, supra note 3.
SAMMDRA included: (1) diminishing what were viewed as unethical marketing practices of international pharmaceutical companies; (2) promoting the practice of prescribing drugs by generic rather than brand names; and (3) legalizing parallel importing of pharmaceuticals. The combined intent of these objectives was to reduce drug costs.

Not surprisingly, large pharmaceutical companies balked, preferring different market prices in different countries, directed to maximize their profits. Pharmaceutical companies waged a campaign to discourage South Africa from parallel importing, asserting that the practice of parallel importing violated their patent protection rights. However, the South African government found nothing in its patent laws consistent with the drug companies' assertions.

In response, the South African government sought to buttress their position by adding the following language to the SAMMDRA as a protective measure: “notwithstanding anything contrary contained in the Patents Act” the Minister of Health can “prescribe conditions for the supply of more affordable medicines.” Those provisions were included in Section 15(c).

As modified, SAMMDRA 15 (c) explicitly authorized both parallel importing and compulsory licensing. It granted the Health Minister power to act in the interest of public health by ensuring that patent rights for any drug would not hinder the South African government from issuing a license to a third party to produce the same drug. It also allowed both cheaper imports from drug producing countries and generic substitution.

III. RESULTS OF SAMMDRA: CURRENT RESPONSES AND POSITIONS ON SOUTH AFRICA'S DRUG POLICIES AS WELL AS SOUTH AFRICA'S AND THE DEVELOPING WORLD'S PERSPECTIVES ON COMPULSORY LICENSING AND PARALLEL IMPORTS

Although drug manufactures in the developed world reap great profits from their products, the basis of that profit margin is on the purchasing power of buyers with distinct endowments. For the most part, customers from developed countries can afford to pay the high costs of the drugs than customers from poorer developed countries. Therefore, one of the most important benefits of compulsory licenses is that they allow lower

17 Nader, supra note 14.
18 See id.
prices for patent protected commodities.\textsuperscript{20} Under a compulsory licensing scheme, governments allow parties other than the patentees to manufacture the patented products. Market competition results, inevitably driving prices downward.\textsuperscript{21} Compulsory licensing, combined with savvy purchasing by interested buyers, has been shown to reduce the prices of some drugs by 30 to 95 percent.\textsuperscript{22}

Compulsory licensing may also be advantageous for technology transfers. It allows third parties to commercialize technology that the original patentees may not have initially exploited or used.\textsuperscript{23} Compulsory licensing is often the only means that allows the patentee's transfer of technology within countries that normally could not import the patented item.\textsuperscript{24}

**EXPLANATION OF TRIPS**

When the World Trade Organization was created, a number of countries signed an agreement known as Trade Related Intellectual Property, or "TRIPS". The TRIPS accord establishes minimum international standards for patents, copyrights and trademarks. The accord also contains specific provisions on compulsory licenses and parallel imports.

TRIPS bars parties from parallel importing on patented items without the permission of the patentee. The TRIPS agreement allows compulsory licensing only when a country abides by the "safeguards" articulated in Article 31. One safeguard requires payment of adequate compensation to patent owners, typically in the form of a royalty or a percentage in sales revenue.

The WHO does not have the authority; however, to adjudicate any disputes that arise from violations of TRIPS. Nonetheless, the accord requires signatories, under specific circumstances, including national health emergencies such as AIDS, to grant a license to local companies, allowing these third-parties to manufacturer patented pharmaceuticals for domestic use.\textsuperscript{25} Moreover, TRIPS does not allow compulsory licensing granted under the public health provision to be challenged under the WTO if pat-

\textsuperscript{20} See \textit{Africa News}, \textit{supra} note 13.
\textsuperscript{21} See Weissman, \textit{supra} note 3.
\textsuperscript{22} See Nader, \textit{supra} note 14.
\textsuperscript{24} See \textit{id}.
\textsuperscript{25} Simon Barber, \textit{AIDS Activists Agenda called into question. Concessions by U.S. Vice-President Al Gore have not stopped protests}, \textit{Business Day} (South Africa), Sept. 3, 1999, at 2.
ented items are imported through channels that are not authorized by the patent-holders.\textsuperscript{26} U.S. policy considers that TRIPS sets the minimum standard of intellectual property protection that signatories have to provide.

\textbf{Pharmaceutical Companies' Perspectives}

Pressure to suppress compulsory licensing and parallel imports which South Africa experienced earlier, stemmed from multinational pharmaceutical companies, which in turn sought U.S. support in waging a global campaign to prohibit countries from dishonoring patent protection rights.

The companies maintained that such practices unfairly infringe on intellectual property rights and diminish corporate profits and the ability to expand R & D efforts.\textsuperscript{27} The U.S. Trade Representative's (USTR) response in the South African example was overwhelmingly supportive of the pharmaceutical industries. That attitude changed when public health and consumer rights advocates alerted the U.S. trade representatives of the alarming death rates associated with AIDS. The advocates highlighted grave public health consequences of U.S.T.R. policy, particularly in relation to the increasing rate of infection and death in Africa. In short, the balance between profits and lives needed leveling.

In May 1999, successful lobbying efforts by public health and consumer rights interests groups promulgated the World Health Assembly (WHA)\textsuperscript{28} to pass a resolution that declared public health concerns "paramount" to intellectual property rights.\textsuperscript{29} Although the United States had previously opposed efforts to pass a similar resolution, on that occasion it did not.\textsuperscript{30}

Although the pharmaceutical companies are opposed to parallel imports and compulsory licensing, such practices are legal by the WTO standards.\textsuperscript{31} Regardless, the United States has a history of joining pharmaceutical companies and actively opposing countries that implement strategies that intended to widen drug access. Revealing the political dimension of the issue, and how important the support of the pharmaceutical companies is on a global scale, the Vice President and former Democratic Presidential nominee Al Gore came out in opposition to efforts to reduce

\textsuperscript{26} See id.

\textsuperscript{27} See AFRICA NEWS, supra note 13.

\textsuperscript{28} This is the policy-making body of the WTO.

\textsuperscript{29} See id.

\textsuperscript{30} See id.

\textsuperscript{31} See AFRICA NEWS, supra note 13.
the cost of life-saving pharmaceuticals in Sub Saharan countries. Public pressure and political interests came to bear to reverse the position of Vice President Gore. He is among those now concerned in addressing public health in trade policies.32

A close examination of U.S. trade policies reveals that the United States practices parallel imports and compulsory licenses in other areas. Ironically, the government regularly issues its own compulsory licenses on pollution control devices, pesticides and computer processing chips.33

Given the United State's own practices with parallel imports and compulsory licensing, trade negotiations surrounding those concerns smacked of "bad faith," specifically with respect to South Africa and their concerted efforts to modify SAMMDRA 15(c).

The recent policy shift on SAMMDRA 15(c) by the United States may acknowledge a dire need to assist South Africa improve its public health crisis (with respect to HIV/AIDS and increase its access to essential drugs).34 Time will reveal if systemic and programmatic changes parallel the United State's recent attitudinal change. Moreover, the future will show whether long-term substantive changes emerge in the United State's foreign policies.

CURRENT RESULTS FROM SAMMDRA

The office of USTR agreed in the fall of 1999 to stop lobbying against South African legislation SAMMDRA. The implication was that South Africa was free to allow local manufacturers to engage in compulsory licensing without U.S. opposition and South African President Thabo Mbeki could authorize parallel importing outside of channels authorized by patent holders in South Africa.35

An amended bill emerged in early 2000 because Pretoria High Court in July 1999 asserted that the previously published Act lacked necessary schedules to control medicinal products.36 As a result of U.S. pressure on South African drug policies, Health Minister Manto Tshabalala-Msimang nevertheless made a decision to "take advice" on SAMMDRA 15(c) in the fall of 1999.

33 See AFRICA NEWS, supra note 13.
34 See Nader, supra note 14.
36 See id.
The upshot of the Health Ministry’s response to SAMMDRA 15(c), which may have been the result of external pressures, is that the South African Manufacturers Association suspended its constitutional challenges to SAMMDRA.\textsuperscript{37} Other intervening factors influenced the course of the legislation. Section 15(c) was undergoing challenges in the Pretoria High Court by the South African Pharmaceutical Manufacturing Association and 41 co-petitioners, including several South African companies and local U.S. and European subsidiaries. The litigants were in the process of negotiating an out-of-court settlement with the Health Minister that considered industry as a partner rather than an antagonist.\textsuperscript{38}

Another intervening factor is that the South African Government recently refused to provide AIDS drugs for pregnant women with HIV. This occurred despite that studies have demonstrated AZT’s effectiveness in reducing by 50\% the risk that the virus would pass on to their babies. An estimated 10\% of babies born each year in South Africa has the virus; transmission in some 35,000 potentially could be prevented by administration of AZT or other drugs.\textsuperscript{39}

Dr. Costa Gazi, a South African health care provider, challenged the government’s refusal to provide anti-AIDS drugs to pregnant women.\textsuperscript{40} The Government’s response was that it could not afford to provide AZT. The cost of screening pregnant women for HIV and subsequent counseling sessions would be approximately $390 – a cost prohibitively high for South Africa.\textsuperscript{41}

Quixotically, President Thabo Mbeki puzzled South African and anti-AIDS advocates in September 1999 by telling parliament that AZT is dangerous, when the drug had been approved by regulators in South Africa and around the world as a treatment for AIDS. Moreover, during spring 2000, Mbeki stated that HIV does not cause AIDS, contradicting conclusions drawn from science, and creating a confusing uproar among public health workers and South Africans. Taking all of these events and attitudes together, it is uncertain what South Africa’s intentions are with respect to

\textsuperscript{37} See id.

\textsuperscript{38} See Barber supra note 35.


\textsuperscript{40} See id.

\textsuperscript{41} See id.
HIV/AIDS policies, despite its new Parliamentary posture on SAMMDRA and U.S. slight easing of pressure.\(^{42}\)

**Compulsory Licensing Permissible Under the WTO**

Although earlier critiques challenged SAMMDRA, under the World Trade Organization, compulsory licensing is permissible as long as the government follows certain procedures to protect the patent holder's interests. Such interests include payments of reasonable royalties, which often receive standard compliance. Moreover, the General Agreement on Tariffs and Trade permits compulsory licensing which is regularly used in industrialized countries including the United States, Japan, and the European Union.\(^{43}\) Parallel imports are also legal under WTO standards.\(^{44}\)

Nonetheless, the United States has repeatedly alleged that the WTO-TRIPS accord does not permit the South African initiatives.\(^{45}\) Yet, the United States refused to bring its concerns under the WTO dispute resolution framework.\(^{46}\) The underlying reason could be that Vice President Gore and the pharmaceutical industries were aware that the South Africans did abide by international trade rules. In fact, United States officials conceded that before the recent USTR policy change, South Africa's policies were permissible by the WTO.\(^{47}\)

Another ironic charge is that the United States, along with most governments, already has the authority to issue compulsory licenses to patented products. For example, the United States can issue compulsory licenses under the Clean Air Act,\(^{48}\) for nuclear power,\(^{49}\) for public health purposes under the Bayh-Dole Act,\(^{50}\) for government use,\(^{51}\) and as a measure for anti-competitive practices under United States antitrust laws.

Furthermore, certain United States leaders are pursuing legalization of parallel import policies in the U.S. Democratic Party. Leaders in the House of Representatives have held briefings to draw attention to a campaign that would relieve prescription drug prices for senior citizens while

\(^{42}\) See id.

\(^{43}\) See id.

\(^{44}\) AFRICA NEWS, supra note 27.

\(^{45}\) Love, supra note 14.

\(^{46}\) See id.

\(^{47}\) See id.


\(^{49}\) 42 USC §2138 (2000).

\(^{50}\) 35 USC §203 (2000).

also criticizing drug manufacturers. Fifty-two Democratic members of Congress who spoke at the briefing all claimed that senior citizens face "discrimination" because companies charge them higher rates than those available to bulk purchasers (such as health maintenance organizations and insurance companies).

Democrats last year introduced a number of bills to enforce reduction in the costs of drugs for the elderly. These Congress members also included bills that would: (1) ensure seniors obtain the same rates as the most preferred customers; (2) force drug companies to give up their patents if they charged too much for drugs; and (3) allow for parallel imports for medicines.

Representative Bernard Sanders (Independent – Vermont) reported that he and a group of Congressional Democrats were interested in allowing parallel imports of drugs from countries such as Canada and Mexico where prices are considerably lower than in the United States. Pharmaceutical companies have challenged the legislative intent by asserting that parallel imports are dangerous because it allows for the importation of substandard unregulated drugs, an issue addressed later in this paper.

**EUROPEAN UNION PARTICIPATION IN THE PARALLEL IMPORT AND COMPULSORY LICENSING MARKETS**

Despite historical resistance from within the United States, parallel imports of pharmaceutical drugs are common in several European countries. In the Netherlands and the United Kingdom, governments provided financial incentives to encourage dispensing of parallel imports. In some instances penalties exist for noncompliance. Parallel trade has developed

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53 See id.

54 See id.

55 See id.

56 There are significant levels of parallel trade in four of the European states: Denmark, Germany, The Netherlands, and the United Kingdom. Also, Sweden and Norway represent country markets in which parallel importing is likely to increase over the next few years. The market sizes in the respective countries are as follows: Denmark: 9%; Germany: 2%; Netherlands: 13%; United Kingdom: 8%. In Germany, pharmacists are reluctant to dispense cheaper drugs, because of the financial disincentives. Therefore, Germany has a low level of parallel imports when compared to other countries. *Dorlands Directories, 1 Med. and Health Care Marketplace Guide* I-661 (1998).

57 See id.
as a result of the enforcement of the European Union's principle of free movement of goods and services. Several features of the European system include: the imposition of a variety of national pricing control programs for pharmaceuticals; price disparity among EC countries; and government programs that cover, at least in part, the cost of prescription drugs.58

Much European import practice involves medicines manufactured in two or more Member States and sold at significantly different ex-factory prices. The parallel trader then purchases medicine in the low price country and exports to the high price country. They are then sold in "parallel" with the same medicine supplied directly from the domestic manufacturer.59

European Community laws affecting parallel trade focus on the importance of free movement of goods and services over patent protection rights. Article 30 of the European Community Treaty establishes the rules governing the free movement of goods and trade. It prohibits "quantitative restrictions on imports and all measures having equivalent effect". Article 36 of the EC Treaty nevertheless provides exceptions to the basic rule by stating that prohibitions or restrictions may be justified on several grounds.60

Article 36 states that "The Provisions of Articles 30 to 34 shall not preclude prohibitions or restrictions on imports, exports, or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants. . . Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. . . . Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States."61

The European Court of Justice has narrowed interpretation of Article 36, asserting that the protection of intellectual property rights should not come under a disguised restriction of trade within the meaning of the treaty.

The official European Union attitude to parallel trade is tolerance. Parallel trade in the Netherlands led to the reference in the European Court of Justice Article 117.62 Subsequent the Article emerged the "De Peijer" judgement. It interpreted the provisions of Articles 30 to 36 and established the legality of parallel imports.63 The European Court of Justice ruled that

58 See id.
60 Jean Pierre Quintin, Treaty of Rome, Trite's et Documents relatifs a' la CEE. (La documentation francaise) (Paris 1984).
62 Supra note 60.
patients can import cheaper over-the-counter medicines for their own use from a pharmacy in another member state, provided that the product is authorized for sale in their own home country.

The European Commission also supports parallel trade. It contributed to a Commission Communication in 1982, and intended to serve as a guideline for national authorities. Subsequently, all national authorities within the European Union have adopted it. The main elements of the Communication closely parallel the holding of the European Court of Justice in the “De Peijer” case. In essence, the importing countries must verify imports are authorized and comply with EU guidelines, as well as adhere to good manufacturing practices in the production of imported goods.64

CANADA

In 1969, Canada amended its Patent Act to authorize compulsory licenses for both the import and the manufacture of patented pharmaceuticals.65 The reasons for the changes included a need to encourage developing a generic drug industry that would help counter the rising rate of pharmaceutical expenditures. The amendments required grants for compulsory licenses for the importation as well as manufacture of drugs.66 A royalty fee was established, while allowing the inventor “due reward” for research and development.67 The results were dramatic reductions in drug prices for Canadian consumers.68

There was strong opposition to compulsory licensing for imports from the research-intensive firms- the “patentees.” At that time, Canada was the only developed country with a compulsory licensing system. With the passage of provincial laws that encouraged generic substitution, research intensive firms faced erosion of market share.69 American Home Products sought an order prohibiting the Commissioner of Patents from taking further proceedings on the pharmaceutical company, Inglis.

67 Frank W. Horner Ltd. v. Hoffman-La Roche Ltd., 61 C.P.R. 243, 245 (1970) (in some instances, up to 4%).
Pharmaceuticals Ltd., with an interest in manufacturing generic drugs. In that case, the court held that section 41(4) of the Patent Act was valid because it pertained to law in relation to patents and not in relation to property and civil rights.

However, in 1987 further amendments significantly restricted broad licensing authority by guaranteeing patentees a longer period of effective patent life. The restrictions aimed at increasing the levels of research and development (R & D) within Canada with the hopeful creation of new jobs. The Canadian Pharmaceutical Manufacturer's Association (PMAC) and the Conservative Tory government supported the Amendments. However, two other major political parties, the Liberal and New Democratic Parties, and the Canadian Drug Manufacturers Association, representing the generic industry, opposed. Concerns centered on future drug prices, as well as whether or not jobs or R & D would increase.

Research-intensive firms committed themselves to doubling their R & D investment from a 4.9% to a10% sales revenue by 1996. They expected to create 3000 new scientific and research jobs which would be a 17% increase, and channel 30% of the new increased levels of R & D expenditures into Canadian Universities, hospitals and research centers.

An updated report concluded that PMAC failed to deliver on the projections mentioned. The percentage of new drugs released between 1991 – 1995 that did not substantially improve therapy, after an average of $89 million was spent yearly on basic research, was 92%. (Compare expenditures with $1billion amount spent per year by pharmaceutical companies in product promotion.) Moreover, the number of jobs eliminated in the brand name pharmaceutical sector (PMAC) was 2,055 between 1990-1995.

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71 Id. at 160.
72 Shulman and Richard, supra note 69 at 745.
73 Id. at 755.
75 Canadian Health Coalition, Bill C-91: A monopoly for drug companies. . . is bad for your health and Medicare <www.discribe.ca/nbnurses/billc91.htex>.
76 See id.
77 See id.
OTHER RESPONSES OF U.S. INTERESTS WITH RESPECT TO PARALLEL IMPORTING AND COMPULSORY LICENSING

In the past few years, the Office of the US Trade Representative (USTR), whose role is to promote American commercial interests abroad, has been an aggressive ally of the drug industry. One objective of the USTR has been to discourage the use of generic drugs abroad through threats of trade sanctions. Although drug costs account for up to 60 percent of the healthcare budget in poor countries, the United States government has allied itself with the interests of brand named drug companies.

As discussed above, in direct response of South Africa’s policy, the United States launched a two-year effort to repeal or modify Section 15 (c) of SAMMDRA. Special U.S. trade task forces organized on the South African issue while Vice President Gore frequently raised patent issues directly with South African officials. There was also bipartisan pressure from the United States Congress.

Furthermore, in February 1999, the U.S. Department of State held a briefing on the global HIV crisis, but disallowed discussions about United States trade pressures on South Africa. In another bout of pressure aimed against South Africa’s policy, the USTR announced on April 30, 1999 a special “out of cycle review” of South Africa’s intellectual property policies to be completed in September 1999 in order to add pressure for legislative changes.

Although the U.S. pressure has subsided in South Africa with respect to drug policies, the United States complained about compulsory licensing and parallel importing as “barriers to trade” at the WHO meeting in 1999. Consistent with other arsenal trade attacks, the comments squarely aimed at warning other developing countries not to pursue policies consistent with those of South Africa. Although South Africa is off the “hot plate”, other nations that have enacted measure permitting compulsory licensing and parallel trade still face vehement opposition from the United States.

For example, the USTR reports on pharmaceuticals reveal that the United States government opposed similar policies in Thailand, Israel and New Zealand. In Thailand, the United States government opposed compulsory licensing, parallel imports, price controls, and government attempts

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78 See The Nation, supra note 1.
79 See id.
80 Love, supra note 14.
81 Africa News, supra note 20.
to collect economic information about drug prices and development costs, measures considered by United States to be barriers to trade.

In response to Israeli policies, the United States government opposed parallel imports, compulsory licensing and the Israeli adoption of the "Bolar" provision which permits the speedier introduction of generic drugs following a patent expiration.\textsuperscript{82} Ironically, this proviso modeled the United States’ policy.

In New Zealand, the United States government declared that New Zealand’s use of reference pricing could adversely affect a pharmaceutical company’s revenue from sales of its patented product. Furthermore, the USTR claims that New Zealand’s practice of using competition to negotiate the best prices, is an obstacle to United State’s trade.\textsuperscript{83}

The results of the seemingly contradictory U.S. trade policy is that on the one hand, the United States is a staunch advocate of freer market economies. Yet on the other hand, and with respect to the pharmaceutical industries, the United States aims to maintain a strong-hand as the dominant price-setter in countries whose poor inhabitants cannot afford to pay artificially exorbitant prices for essential drugs.

Moreover, United States drug-trade policy lags significantly behind what may well be political rhetoric. In the September 1999 annual address at the United Nations Assembly, U.S. President Bill Clinton stated he would pledge to do more to ensure that HIV-positive mothers in developing countries have access to drugs which diminish the likelihood of transmitting the AIDS virus to their children.\textsuperscript{84}

Clinton stated he would convene a White House meeting of pharmaceutical CEOs, charitable foundations and the scientific community to consider ways to confront the fact that only 2% of investments in vaccine research was for diseases that afflict the poor.\textsuperscript{85} Clinton added that improving health care in the developing world should be a part of "an unrelenting battle against poverty and shared prosperity".\textsuperscript{86} Albeit meaningful intentions, a White House meeting falls short of the dire need of legislative and executive changes in U.S. drug trade polices. No concrete policy proposals emerged from that discussion at that time.

However, a United Nation’s meeting occurred in Spring 2000 where Vice President Gore addressed South Africa’s public health issue, and stated that $150 million was being pledged by the United States Con-

\textsuperscript{82} Love supra note 14.
\textsuperscript{83} See id.
\textsuperscript{84} See id.
\textsuperscript{85} See id.
\textsuperscript{86} See id.
gress for combating the epidemic in Africa. Critics claim, however, that this amount of aid is shy of what is necessary to combat the problem, when compared to the billions of dollars spent on the war actions in Bosnia.

Public Response to the U.S. Actions

Public health advocates argued United States trade officials acted in “bad faith” when they told South Africa that any legislation providing for compulsory licensing of patents of patented products on public health grounds was a violation of the TRIPS. They reasoned that Article 27.1 of the TRIPS states that patent rights should be enjoyed “without discrimination as to . . . the field technology,” and that any special program for compulsory licensing on public health grounds is discriminatory.

Experts at the WTO and WHO took another view of the TRIPS provision. They claimed there was wide latitude in TRIPS to provide for compulsory licensing under Article 31 on many public interest grounds, while maintaining the safeguards and requirements of remuneration. Furthermore, past U.S. pressure on South Africa, and its current policies maintained toward other countries, are considered “bad faith” by these experts — given the United States’ own statutory programs for compulsory licensing under the Bayh-Dole Act, the Clean Air Act, and Nuclear Energy Act.

The Protection of Pharmaceutical Patent Rights

In the 1980s, Congress enacted the Bayh-Dole Act and the Stevenson-Wydler Technology Innovation Act, later amended as the Federal Technology and Transfer Act of 1986. The primary purpose of the laws was to bolster U.S. competitiveness, while encouraging commercialization of basis research discoveries. The Act provided federally funded incentives for private sector investment. The Department of Health and Human Services (DHHS) designated the NIH as the lead agency for the technology transfer for the Public Health Service (PHS).

89 See id.
90 See id.
91 See supra notes 48, 49, 50.
92 See id.
93 See The Nation supra note 1.
With respect to inventions developed through NIH funding, the Bayh-Dole Act allows NIH grantee contractors the authority to retain title to patents and to license inventions that result from the NIH funding.\textsuperscript{94} Although the NIH is responsive to the economic development intent of the legislation, it carries out its role along side its public health mission. The PHS patent policy provides protection where further research and development acutely recognizes the technology’s primary use and its future for effective therapeutic diagnosed prevention. Exclusive licenses are granted when patent rights guarantee product development. It is rare that technologies develop without some form of exclusive protection.

Protection is key to the pharmaceutical industry because development costs for bringing the product to the market are too high. It takes approximately fourteen years to market a successful drug and the costs generally exceed $360 million.\textsuperscript{95} Although the U.S. government funds basic research at a limited level, some critique the amounts are inadequate.\textsuperscript{96} Investors require a significant amount of private investments to conduct the studies and pipeline research required for just one successful drug against the many failures.\textsuperscript{97}

Because there are few gains when a technology does not reach the market place, patent exclusivity is often justified. It is the pay-off and the incentive for the inventor’s investment. Critics assert that market exclusivity safeguards investments by assuring pharmaceutical manufacturers the ability to charge considerably higher prices than the cost of manufacturing alone.\textsuperscript{98} Despite imperfection, this system resulted in many useful pharmaceuticals.

An economic assumption is that companies would not undertake development costs of inventions if they believe the government would allow third parties to practice inventions. Accordingly, the wisdom of transferring manufacturing or distribution rights to the WHO or any other nonprofit organization is not certain. This is why pharmaceutical advocates argue that successful technological transfer requires that the Government protect intellectual property rights. Otherwise, undermining intellectual property rights may dampen development of essential drugs.

\textsuperscript{94} See id.
\textsuperscript{96} See id.
\textsuperscript{97} See id.
\textsuperscript{98} See id.
Drug companies have experienced a decline in their stock value and these companies point to parallel imports as a significant factor in this decline. For example, Adock Ingram experienced a decline in their shares in September 1999 and claimed it was due to compulsory licensing and parallel import effects.99

Glaxo-Wellcome said parallel imports were already costing the company “tens of millions a year”. Glaxo claims that were it not for parallel trade, it clearly would have had more resources available to research new medicines.100 Moreover, pharmaceutical companies assert that parallel import and compulsory licenses curtail profits and reduce incentives for research and development.

On the other hand, although providing incentives for research and development is vital, many policies aimed at widening access to drugs do not quantitatively and significantly affect research and development incentives.101 For example, Africa is approximately only 1.6 percent of the global market for pharmaceutical purchases. Therefore, for most drugs, especially for high-priced drugs, Africa is not a significant determining factor for research and development efforts. Similarly, for high-priced drugs that currently have no significant impact on domestic sales due to prohibitive costs, compulsory licensing is likely to increase revenues from that market by increasing sales volumes due to scale.

What then disturbs South African drug companies over legislation such as SAMMDRA? The main concern of the pharmaceutical industry is the marked contrast of selling a drug such as Fluconazole in Italy for $23.50, but for only $0.95 in India. In short, companies may well be concerned that cheap prices for pharmaceuticals in Africa may undermine another country’s willingness to pay high prices, for example in the U.S. or European markets.102 That in turn would dampen worldwide profits.

ECONOMIC EFFECTS OF PARALLEL IMPORTS

Given the price disparity of pharmaceuticals as delineated in the previous section, one may begin to understand that parallel trade is a form

99 Tammy Lloyd, Someone’s in Need of a Good Dose of Salts, FINANCIAL MAIL (South Africa), Sept. 24, 1999, at 70.
101 Love, supra note 14.
102 See id.
of imperfect arbitrage. The objective is to reduce price differentials to more than the transaction costs of the arbitrage. Under parallel trades, often the costs of the transaction include repackaging, relabeling, licensing and transportation.

The effects of increased competition in most markets would increase economic efficiency. This is because increased competition results in undercutting the high cost and inefficient producers. However, this is not the case in the pharmaceutical industry.

The pharmaceutical producers that invest in R & D are at a short-term economic risk. The start-up costs are high and new market entrants do not bear those initial costs. Therefore, arbitrage with respect to the pharmaceutical industry is damaging to long-term economic efficiency.

Accordingly, parallel trade magnifies the consequences of one country holding price levels below economic cost of medicine production. This is because prices all across the trading states would be the same.

Within the European Union, price equalization benefits from the outcome of competition and the free movement of goods. However, where there are substantial fixed costs, including research and development for pharmaceuticals, then some economists suggest that the economic arguments against forcing the equalization of prices become apparent.

For one, price averaging would increase prices for poorer countries. Such countries may be unable to sustain the same level of purchase price and quantity that high-income countries can afford. Inevitably, they argue, patients will suffer. Second, some economists contend that price equalization involves an indirect transfer of money from poor countries to rich ones.

There are counter arguments to both of the proposed assumptions. The first argument assumes an average price above marginal cost. However, prices resulting from parallel trade could reflect either at marginal cost or below marginal cost, both of which would capture the greater market share, rendering above marginal cost prospects unlikely (unless there is collusion).

104 See id.
105 See id.
106 See id. at 134.
107 See id. at 134.
108 See id. at 134.
109 See id. at 131-136.
Furthermore, the economists do not explain how equalization reflects an indirect transfer of funds from poorer to richer countries. Simply because there has been the effect of averaging does not necessarily mean that the mathematical consequences average as such with respect to trade. Although richer countries pay lower prices, it is not at the expense of the poorer countries that do not recognize benefits from lowered prices. In fact, because of their average income, higher income countries benefit more. Accordingly, there may be no indirect transfer of resources from poorer to richer countries as the economists suggest. If anything, the transfer results from richer countries subsidizing the consumption for poorer countries, because it is the rich countries that can afford the research and development, manufacturing and the distribution of drugs. It is the poorer countries that benefit from these fixed costs at the "expense" from the rich.

Moreover, because the intended consumers presumably cannot afford the drugs at costs that it would take to account for R & D costs, these sales could otherwise be lost. It is therefore difficult to see how this scheme would negatively affect a patent holder's return of investment when the choice may diminish to either sales at a reasonable price or no sales at all.¹¹₀

**The Industry Claims Disadvantages for Developing Regions:**

Drug companies claim parallel trade can be dangerous. Drugs may deteriorate through poor handling, and they often become contaminated during repackaging. Moreover in some countries with lax controls, drugs have been given to English speaking patients with Spanish or Italian instructions.¹¹¹

The South African Parliament recently stated that the introduction of parallel imports could lead to an influx of counterfeit and substandard drugs. Failure to subject these imports to the same rigorous controls as locally manufactured products could lead to a barrage of second rate medicines. Due to the vagueness of the legislation, the South African health minister has wide powers to regulate health care without following the parliamentary debate process.

According to the pharmaceutical group Adcock Ingram, the company’s latest annual report stated the benefits flowing from parallel imports of cheaper medicines were questionable.¹¹²

Pharmaceutical companies criticize compulsory licensing for producing substandard drugs when manufactured by the licensee. Although

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¹¹₀ Murashige, *supra* note 95.
¹¹¹ *Supra* note 100.
¹¹² *Supra* note 99.
generic purity and effectiveness standards can be insured through "bioequivalence testing," developing countries struggle in achieving competent results. For example, although Brazil recently passed the Generics Law, which authorizes the generic production of brand name drug products, there are currently only four laboratories in Brazil with the capacity to conduct bioequivalence testing.\textsuperscript{113} The Government has admitted "that the current structure is still precarious, due to the complexity and cost" of the tests.\textsuperscript{114}

**How Europe Deals with Quality Control of Parallel Imports**

Parallel importers in the European Union focus on the latest, best selling patent-protected lines. The centralized European procedure for registration [carried out by the European Medicines Evaluation Agency (EMEA)] has an affect in that area, and most likely will be the normal regulatory route for most new and therapeutically innovative medicines in the future.\textsuperscript{115}

Because of the evaluation carried out by the EMEA, centrally approved medicines have single "Summary of Product Characteristics," labeling, packaging and patient information leaflets in all official European Union languages. As a result, language-specific texts are approved and available for parallel importers to use.\textsuperscript{116}

The US public interest position on the matter centers on economic equity. Given the United States government (through its tax base) contributes to the development of a significant portion of essential drugs, (such as those that remedy HIV/AIDS),\textsuperscript{117} it is therefore unwise to inflate the prices of essential drugs when companies, not taxpayers, reap direct economic profits. This position has garnered much criticism, as well as generated global support and pressure for alternative solutions.

**Examining the Possible Alternatives**

*Enacting WHA-EB103/4*

In light of the current U.S. stance on parallel imports and compulsory licensing in South Africa, the global health community is now mobilizing to have the USTR adopt a broader global view in its trade policies with respect to public health.

\textsuperscript{113} Brazil Passes Generics Legislation, MARKETLETTER, Sept. 6, 1999.
\textsuperscript{114} See id.
\textsuperscript{115} See supra note 103.
\textsuperscript{116} Supra note 103.
\textsuperscript{117} See id.
In May of 1999, the World Health Assembly (WHA) enacted a “Revised Drug Strategy” resolution: (EB103/4). The resolution passed with U.S. government support and requires member countries to:

1. Reaffirm their commitment to developing, implementing and monitoring national drug policies and to take all necessary concrete measures in order to ensure equitable access to essential drugs;
2. Ensure that public health interests are paramount in pharmaceutical and health policies;
3. Explore and review their options under relevant international agreements, including trade agreements, to safeguard access to essential drugs.\(^{118}\)

To date, the Resolution has not been implemented. Under EB103/4, a policy review should have been conducted on essential issues. For example, the U.S. government has requested countries to limit the scope of compulsory licensing to cases involving anti-competitive practices, national emergencies and air pollution control.\(^{119}\)

U.S. position at this point is inconsistent. In Thailand, where there are at least one million HIV/AIDS patients, the U.S. government has opposed the use of compulsory licensing of HIV/AIDS drugs. Accordingly, the U.S. should reconsider its opposition to compulsory licenses in Thailand where public health groups such as Medicines Sans Frontier support the use of compulsory licensing to acquire drugs such as ddI, 3TC, d4T or Novir to combat AIDS. In essence, the USTR should consider extending the policy held in South Africa to all developing countries.\(^ {120}\)

**Allowing the WHO the Right to Health Care Patents Held by the U.S. Government**

The global public health community has proposed that the NIH enter into an agreement with the WHO to allow the WHO the right to use health care patents held by the U.S. government.\(^ {121}\)


\(^{119}\) See id.

\(^{120}\) See id.

The U.S. government holds public use rights on government spurned inventions, which include many important AIDS drugs, such as ddl, d4t, 3TC or Ritonavir, and other medicines.\textsuperscript{122}

Based on the principle of "public use technologies," consumer advocate groups claim that it is possible for the United States to retain the right to practice the invention on behalf of any foreign government or international organization that is a signatory to any existing or future treaty or agreement with the United States.\textsuperscript{123} This may follow, because the United States retains rights on inventions that they fund through grants and contracts at universities and small businesses under the Bayh-Dole Act. Moreover, the U.S. government has an eminent domain right to practice patented technology.\textsuperscript{124} "This is indistinguishable from a compulsory license."\textsuperscript{125} Therefore, according to consumer rights advocates, the U.S. may have worldwide rights to practice or have practiced inventions on its behalf. Moreover, the U.S. may require that foreign governments or international organizations have the right to use inventions under 37 CFR 401.14.\textsuperscript{126}

Although many public health groups have pressured the Vice President and other Administration officials to support efforts to give the WHO the right to practice these inventions in poor countries, the U.S. has declined to do so. The Government has its reasons. The then Director of the NIH, Dr. Harold Varmus, attests that the Government’s royalty-free license allows it to have no-cost use of a technology it invented or funded. However it does not provide rights or access to a licensee’s final product. However, allowing the owner of the technology, or the licensor the ability to conduct further research is often provided in the context of an exclusive license.\textsuperscript{127}

Further, microeconomic theory reveals that compulsory licensing will increase sales as prices decrease. Accordingly, some believe that these policies will not harm industry earnings to the extent that drug companies

\textsuperscript{122} See id. (The relevant statutes and regulations are 35 U.S.C 202 (c)(4) of the Bayh-Dole Act and 37 CFR 404.7, where the government allows public use rights on inventions). See also Murashige supra note 95.

\textsuperscript{123} Love, supra note 14.


\textsuperscript{125} Murashige, supra note 95; see also Florida Prepaid v. College Savings Bank, 527 U.S. 627 (1999). (Where it appeared that any state could manufacture drugs for its citizens without paying royalties).

\textsuperscript{126} Nader et. al., supra at 118; see also supra note 14.

\textsuperscript{127} Dr. Harold Varmus, Letter from NIH Director, to Ralph Nader, James Love, and Robert Weissman (responding to their request calling on the NIH to provide the WHO access to US government funded inventions) (Oct. 19, 1999) <http://www.cptech.org/ip/health/hsa/varmusletteroct19.html>.
As compulsory licensing expands access to AZT and ddI in Africa and in developing regions without reducing prices in the U.S. and Europe, then companies could gain in revenues. This is because drug sales in developing regions are low because prices are too prohibitive.

Although it is believed by consumer advocacy groups that the United States can license patent rights to the WHO, there are nevertheless, doubts regarding WHO’s authority to practice inventions under the Government use license. Moreover, leadership within the NIH attests that it does not necessarily have to intervene on behalf of a foreign country when that intervention is (1) unsolicited and (2) alternatives exist for those countries to achieve results similar to those that may result under compulsory licensing. Such alternatives may place the current system at risk without necessarily allowing greater accessibility to essential drugs by developing regions. Consequently, action under the WHO and the NIH, with respect to NIH supported patent rights, are unlikely.

GLOBAL ACCESS TO DRUGS AS A FUNDAMENTAL RIGHT

The AIDS crisis in South Africa and in developing countries is a public health problem that encompasses much broader issues than access to anti-viral drugs. The drug supply issue must be weighed against other equally important issues such as public health programs, treatment, monitoring compliance, medical infrastructure, and the emergence of drug resistant HIV-strains. Nevertheless, there exists a need to confront methods of gaining access to vital drugs.

In terms of market revenue, the developing world markets are a very small income source for the pharmaceutical industry. The market represents only about 10% of international sales and just 1.6% in the continent of Africa. Despite that, drug companies would prefer the freedom to set any pharmaceutical price they deem fitting. Is it reasonable to allow such free domain to any entity that controls life saving technologies?

Liberalization of pharmaceutical patent rights is a fundamental human right. Support for human rights and social welfare is found in Article 3 of the Declaration of Human Rights. It states “[e]veryone has the

128 See id.
129 See id.
130 See id.
131 See id.
132 Varmus, supra note 127.
133 See id.
134 AFRICA NEWS, supra note 20.
right to life, liberty, and security of person. . ." Moreover, Article 12 of the United Nations' Covenant on Economic, Social and Cultural Rights, lays a proper foundation for sound public health policy with respect to intellectual property rights. The covenant includes the right of everyone to the "enjoyment of the highest attainable standard of physical and mental health." Although the United States is not a signatory to Article 12, the United States traditionally has lobbied foreign governments to adhere to principles upholding "human rights." In fact, the United States has levied sanctions against countries it deems guilty of human rights abuses.

**Proposals:**

Given the seeming inconsistency of foreign and trade policies, the U.S. should reconsider its approach toward other countries pursuing WTO legal policies, such as compulsory licensing and parallel trade. These countries include, but are not limited to Thailand, Brazil, Argentina, India, and Israel. The U.S. should lift all enacted sanctions against countries in direct retaliation for pursuing any intellectual property policies aimed at addressing urgent public health needs, such as those associated with HIV/AIDS. The U.S. should recognize that creating wide powers for granting compulsory licenses is not in contradiction of TRIPS-WTO. It is actually a component of the United States domestic laws.

**Summary**

This article examined South Africa's challenge in combating its growing HIV/AIDS epidemic. In passing SAMMDRA 15(c), the South African government protected its right to institute parallel trade and compul-

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137 Past and current economic embargoes by the United States include but are not limited to Cuba, Iraq, Libya, and Nicaragua, all under claims which include allegations of human rights abuses.
139 Nader et. al., *supra* note 118; see also, *supra* note 16.
EXAMINING GLOBAL ACCESS

The government aimed to provide wider access to drugs, most of which combat HIV/AIDS.

The United States, acting as an agent of multinational pharmaceuticals, sought to retain profits and protect patent rights. Both bodies pressured South Africa to change its laws. After sustained worldwide efforts among consumer interest and public health advocates, the United States government relented and changed its position on SAMMDRA 15(c). South Africa has followed suit by altering SAMMDRA 15 (c) to more closely resemble Articles in GATT. Nonetheless, the South African policy was already legal under TRIPS and proved to usher in large-scale health benefits through cheaper and wider access to essential drugs.

Since the policy shift of the United States, South Africa has been reevaluating its own public health strategy in a seemingly quixotic manner. However, it at least seems it is free to do so without outside pressure. Moreover, South Africa has also sought to deliver Diflucan; an HIV/AIDS related treatment, free of charge to AIDS patients. Given that South Africa prevailed in preserving its compulsory licensing and parallel imports, the same case could be made with other countries in desiring access to cheaper drugs.

Parallel imports and compulsory licenses in the developing world do not affect companies’ revenues significantly. However, public health benefits are enormous. For the protection of fundamental human rights, the U.S. should reconsider its global trade policies of essential pharmaceuticals and implement strategies that place public health concerns “paramount” to intellectual property issues.

Pfizer plans to give fluconazole free to South African AIDS Patients, MARKETLETTER, Apr. 10, 2000. (Where Pfizer sent a letter to the Treatment Action Campaign in South Africa that an “appropriate response to the HIV/AIDS epidemic must be made with consideration for safe, ethical treatment, in full coordination with the South African government, and through appropriate medical infrastructure.”).