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ONE HUNDRED SIXTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

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July 16, 1999

The Honorable Charlene Barshevsky
Ambassador
United States Trade Representative
600 17th Street, N.W.
Washington, DC 20508

Dear Ambassador Barshevsky:

On July 12, 1999, I sent a letter of invitation to you requesting that you or your representative testify before the Subcommittee on Criminal Justice, Drug Policy and Human Resources on the topic of: "The U.S. Role in Combating the Global HIV/ AIDS Epidemic." Subsequently, a meeting was held involving members of our staffs, in preparation for the hearing. I am most surprised and very dismayed to learn today that you have apparently decided not to have anyone from your office testify at our hearing on this critical issue.

You are quite aware of the magnitude and importance of this issue internationally, and of consequences that impact, or stem from, our trade policies. The Office of the U.S. Trade Representative has important responsibilities in this issue. Accordingly, I am reissuing my invitation to you or your representative to testify before this Subcommittee on this issue, with a definitive response from your office due by Monday, July 19th. Should you fail to comply with this request, it is my intention to pursue a subpoena to ensure that you provide necessary testimony, witnesses and records that meet our informational needs. This is a life and death issue to millions of persons globally, and has important impacts on our international trade and humanitarian policies.

If you have further questions, please contact me or members of my Subcommittee staff (Sharon Pinkerton, Deputy Staff Director ~~or Steve Dillingham, Special Counsel~~).

Sincerely,

John L. Mica
Chairman
Subcommittee on Criminal Justice, Drug Policy and Human Resources

Amendment to H.R 2415 - Title VIII - Intellectual Property or Competition Law Relating to Pharmaceutical or Other Medical Technologies in Sub-Saharan African Countries

Department Position: Oppose

Talking Points

- Intellectual property protection is fundamental to U.S. research based pharmaceutical firms in order to ensure continued innovation.

- This proposed amendment would undermine intellectual property protection and the incentive to innovate and to develop new drugs. It is also contrary to U.S. Trade Policy as articulated in Title III Chapter 1 Sections 301 - 310 of the Trade Act of 1974 as amended.

- For example, Congress has always recognized that TRIPS (Trade Related Aspects of Intellectual Property Rights) is a set of minimal standards, a lowest common denominator assessment, in many instances below U.S. standards. Therefore, Congress urged us to seek IPR protection from other countries at levels higher than those provided in TRIPS. Section 301(d)(3)(B)(I)(II) Definitions and Special Rules specifies that "acts, policies and practices that are unreasonable include" those which deny fair and equitable "provision of adequate and effective protection of intellectual property rights notwithstanding the fact that the foreign country may be in compliance with the specific obligations of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) referred to in Section 101 (d) (15) of the Uruguay Round Agreements Act."

- The State Department plays a crucial role in protecting intellectual property world-wide. This includes working with the Office of the United States Trade Representative to determine if countries offer adequate and effective intellectual property protection to U.S. rights holders as described in the statute. In addition Department of State, through its embassies and consulates works to implement decisions taken in the Special 301 determinations.

- On the issue of competition law, the Department of Justice and the Federal Trade Commission under the authority of the Sherman Anti-Trust Act, the Clayton Anti-Trust Act and Federal Trade Commission Act need to work in cooperation with the Department of State in all international anti-trust matters. It is with the assistance of our embassies that civil and criminal investigations of anti-competitive practices are initiated.

Drafted: EB/IPC:Scronin
Cleared: EB/TPP:WCRAFT
EB/IPC:Twalsh
L/EB:JBrooks

27

AMENDMENT TO H.R. 2415

OFFERED BY MR. SANDERS OF VERMONT

Page 35, after line 9, insert the following (and conform the table of contents accordingly):

SEC. 211. PROHIBITION ON INTERFERENCE WITH INTELLECTUAL PROPERTY LAW RELATING TO PHARMACEUTICALS OF CERTAIN FOREIGN COUNTRIES.

No employee of the Department of State shall take any action to deter or to otherwise interfere with any intellectual property law or policy of any country in Africa or Asia (including Israel) that is designed to make pharmaceuticals more affordable if such law or policy, as the case may be, complies with the Agreement on Trade-Related Aspects of Intellectual Property Rights referred to in section 101(d)(15) of the Uruguay Round Agreements Act (19 U.S.C. 3511(d)(15)).

BRIEFING

July 14, 1999

MEMORANDUM FOR AMBASSADOR RICHARD FISHER

THROUGH: Joseph Papovich

FROM: Claude Burcky/Geralyn Ritter/Kent Shigetomi

SUBJECT: Your meeting with Congresswoman Schakowsky and Congressman Berry

ISSUE:

On July 15, you are scheduled to meet with Congresswoman Jan Schakowsky (D, Ill.) and Congressman Marion Berry (D, Ark.) to discuss IPR policy towards South Africa. Berry is a member of the Prescription Drug Task Force and a co-sponsor of HR 1885, which would authorize parallel imports of pharmaceuticals. The two are concerned that the Administration is pressuring South Africa into refraining from compulsory licensing and parallel importation of HIV/AIDS drugs to curb the epidemic there. You should highlight (1) USTR's legitimate concerns about protecting patent rights and maintaining the safety and efficacy of pharmaceuticals, and (2) USTR's efforts to develop a mutually acceptable solution with the SAG and the chances for achieving this at a July 28 TIFA that would accept parallel importation and compulsory licensing provided certain conditions were met.

TALKING POINTS

- The government of South Africa is trying to improve access to quality health care for its people. This is a goal we fully endorse and support. We see no conflict, however, between intellectual property protection, sound public health and access to essential drugs.

- We have been concerned about provisions in the South African Medicines Act that would grant the Health Minister broad unspecified powers to abrogate patent rights for pharmaceuticals and permit parallel imports.

- We are trying to resolve our differences with South Africa. The Administration has proposed a framework for resolving our differences concerning the Medicines Act.

- These talks have been complicated, however, as both sides were cautious that our discussions not prejudice legal proceedings in which domestic and international firms are challenging the Medicines Act in a South African court. Although these talks have not resulted in a resolution of our differences, we are confident that continued discussion will result in a mutually satisfactory conclusion.

- Our two governments have scheduled a video conference for July 28 to address this and other trade issues.

- Because of their very nature, pharmaceutical imports are complicated by special health and safety concerns that are valid in every market. The manufacture and shipment of pharmaceuticals must be carefully regulated to ensure safety and efficacy. This becomes more complicated when drugs leave authorized distribution networks.

- There is a risk that pharmaceuticals, including antibiotics and HIV/AIDS drugs, may become damaged. There is also the risk that information about these drugs will be lost such that they will not be administered to patients correctly, and inappropriate use will lead to antimicrobial resistance with powerful new forms of drug-resistant organisms.

- We know that other countries, including some in Africa, have experimented with parallel importation of pharmaceuticals and have found that it was too difficult to ensure the safety and efficacy of such medicines.

Questions and Answers: South Africa and IPR

Q: Does the U.S. consider parallel imports a violation of trade agreements?

A: Our position is that the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) contains provisions that grant patent holders certain rights, one of which is the exclusive right to control the sale and importation of the patented product (Article 26). The Agreement also contains a number of provisions requiring effective enforcement of intellectual property rights, including at the border. So, in our view, parallel imports are prohibited. However, Article 6 of the Agreement states that issues related to the exhaustion of rights, such as parallel imports, are not covered by WTO procedures governing dispute settlement.

Q: On the issue of parallel imports, why is the Administration hounding only smaller countries, like South Africa, while leaving alone big countries, like the European Union?

A: The U.S. opposes policies that promote parallel imports of certain patented and copyrighted products. We have pursued this policy with a number of countries, including Israel,

Australia, and New Zealand. Critics of our policy have argued that the European Union permits parallel imports. It is important to note that parallel importing is permitted *only within the 15 member states of the European Union*, and not from outside the Union. For example, a drug produced in Germany can be exported to France, and then re-imported for sale back into Germany, given that the EU is a customs union. Under EU regulations, that same German manufacturer cannot export his product to the U.S.--or any other non-EU country--and then re-import it back into Germany because the U.S. is not a member of the EU.

Q: What provision of the Medicine Act is the Administration seeking to change?

A: We are concerned that Article 15(c) of the Medicines Act grants the Health Minister broad and unspecified powers to abrogate patent rights. Article 15(c) could conceivably be used by the Health Minister to weaken the South African Patent Law. The United States has consistently asked for clarification on two points. First, we have sought assurance that South Africa would use the Medicines Act only to engage in compulsory licensing and parallel importation of pharmaceuticals, and not in any other way that would undermine patent rights. Second, we want the South African Government's assurance that if it engages in compulsory licensing it will do so in a manner consistent with TRIPS. Similarly, if it engages in parallel importation, that it will do so in a manner that is not otherwise inconsistent with TRIPS, and in a way that would preserve the safety and efficacy of the pharmaceutical products themselves.

BACKGROUND:

South Africa amended its Medicines Act in December 1997 to grant the Health Minister broad, unspecified powers to abrogate patent rights for pharmaceuticals and to permit parallel imports. A coalition of South African and foreign companies is challenging the legislation in court, and so the law has never been implemented. Since the amendment, the U.S. has asked the SAG to affirm the Medicines Act would only be implemented in a manner consistent with the SAG's TRIPS obligations.

USG agencies have had to navigate between competing constituencies. On the one hand, the pharmaceutical industry has asked the USG to pressure the SAG into repealing or amending the Medicines Act. In the closing days of last year's budget process, Congressman Frelinghuysen of New Jersey slipped into the foreign aid bill a provision that blocked U.S. aid to South Africa until the State Department explained what it was doing on industry's behalf. Dissatisfied with the first report, Congress asked for a revised report containing language that portrayed U.S. efforts as more aggressive. During this year's Special 301 review, PhRMA recommended that South Africa be elevated to Priority Foreign Country. Achieving interagency consensus to keep South Africa on the Watch List was difficult and was achieved only on the assurance that the USG would use every available forum to press the SAG for reform. The SAG has bristled at being on the Watch List and has complained that it discourages foreign investment.

At the same time, a coalition of NGOs has been pressuring the USG—and especially the Office of the Vice President—to view the situation in light of South Africa's AIDS epidemic. These groups have argued that human lives are far more important than pharmaceutical company profits, and that the USG should permit the SAG to do what (they believe) the TRIPS Agreement already allows South Africa to do, that is, engage in parallel importation and compulsory licensing of pharmaceuticals.

In an effort to find a way out of the morass, USTR developed a set of IPR benchmarks to lay out what we expected of the SAG. One set dealt specifically with the pharmaceutical issue, and the remaining benchmarks covered other IPR concerns, including TRIPS implementation, and cooperation within the World Health Organization (WHO). These benchmarks call on the SAG to reaffirm its commitment to implement the TRIPS Agreement by the January 1, 2000 deadline. They acknowledge the SAG's efforts to improve access to quality health care and asks the SAG to reaffirm that its policies and practices with respect to pharmaceuticals shall be fully consistent with its TRIPS obligations. It specifically states that the if the SAG should engage in compulsory licensing, it will do so in a manner consistent with Article 31 of TRIPS. If the SAG engages in parallel imports, then it will do so in a manner consistent with TRIPS that does not undermine enforcement of patent rights, and that ensures the safety and efficacy of the pharmaceuticals.

We proposed that if the SAG could commit to the pharmaceutical benchmarks, we would consider the matter closed and it would no longer figure into our Special 301 process. We would reserve the right, of course, to revisit the issue pending the outcome of the litigation and the manner in which South Africa implements the Medicines Act. The initial SAG reaction has been one of suspicion. Our embassy has reported that certain officials agree with the general language of the benchmarks, but question what form an affirmation should take. Other officials have asked about the connection between a SAG affirmation and its removal from the Special 301 Watch List. A TIFA to discuss these issues will occur on July 28.

On June 25, in a response to a letter from the Chairman of the Congressional Black Caucus, the Vice President wrote that he supports "South Africa's efforts to enhance health care for its people -- including efforts to engage in compulsory licensing and parallel importing of pharmaceuticals -- so long as they are done in a way consistent with international agreements." The NGOs believe that USTR and other agencies will use the phrase "consistent with international agreements" to continue to adhere to their interpretations of TRIPS, namely that the agreement prohibits parallel imports.

FAX COVER SHEET

Joe Paporich
Claude Burkey
Mike Koplovsky

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Office of Services, Investment and Intellectual Property

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From: Kent Shigetomi (Section 19)

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Subject: From Joe Paporich - briefing material on S. Africa

TESTIMONY ON THE PROTECTION OF US INTELLECTUAL PROPERTY ABROAD, PARTICULARLY WITH RESPECT TO SOUTH AFRICA

House Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy and Human Resources

July 21, 1999

Mr. Chairman:

Thank you very much for inviting us to testify on intellectual property policy in South Africa.

This hearing focuses on a topic that is of crucial importance to the health and future of millions of people in Africa and elsewhere: the role of our policy in ensuring access to effective medicines for AIDS and other illnesses. The Administration, together with our partners in South Africa and elsewhere, has developed a policy which ensures to the maximum degree possible access to current medicines to treat AIDS, while providing the incentives that will speed the development of effective medicines that in the future have the potential to cure or prevent the disease.

This policy has, on the whole, benefited both American patients and patients around the world. It has helped ensure a financial return on successful medicines, which in turn has funded additional research, and thus given patients a continuous supply of new medicines to treat previously deadly or debilitating conditions.

Over the years, however, these incentives have been eroded by piracy and counterfeiting overseas. Once a process or compound has been developed through expensive and time-consuming experimentation, and its efficacy and safety assured by FDA testing, competitors can duplicate the innovator's work at very little cost.

THE "TRIPS" AGREEMENT AND "SPECIAL 301"

A top priority of our work in the so-called Uruguay Round negotiations in the World Trade Organization was to secure adequate and effective patent protection for American pharmaceuticals worldwide. In this we succeeded: all WTO members committed, through the Agreement on Trade-Related Aspects of Intellectual Property Rights (or "TRIPS") to provide, after varying transition periods, inventors and creators with the right to protect their intellectual property, including the right to obtain pharmaceutical patents. Over time, the result will benefit both producers and users as, in the case of pharmaceuticals, companies in the U.S. and overseas are given greater incentives to research and produce new medicines to continue the fight against disease. Implementation of the TRIPS Agreement, including its provisions affecting pharmaceuticals and other patented products, has become an important part of the Administration's trade agenda.

Another important component of USTR's policy is the so-called "Special 301." The Special 301 provisions of the Trade Act of 1974 require the USTR annually to identify foreign countries that deny adequate and effective protection of intellectual property rights and to issue a public report to this effect at end of each April. In the report, countries are placed on lists, ranging from most egregious, where sanctions may ultimately be involved, to a watch list, where we literally monitor the situation and urge improvements. Special 301 was amended by Congress in the Uruguay Round Agreements Act to clarify that a country can be found to deny adequate and effective intellectual property protection (and thus placed on one of these lists) even if it is in compliance with its obligations under the TRIPS Agreement.

Each year USTR, in consultation with other agencies, examines the level of intellectual property protection afforded by our trading partners. We analyze legislation, enforcement activity, and market trends to arrive at our determination. We draw on the reporting from our embassies and consulates overseas, but we also receive input from industry associations, individuals, and even foreign governments.

In some instances, we agree with the recommendations of those outside of the government; in others we do not. For example, during this year's Special 301 review, there were recommendations to designate South Africa as a "Priority Foreign Country," which could have resulted in trade sanctions. We chose not to do so, however, because we did not agree with the magnitude of the problem and because we had already developed a framework to resolve our differences which we are confident will work.

PATENT POLICY AND AIDS

Let me turn now to the AIDS/HIV crisis and how it relates to intellectual property protection. Until the recent development of protease inhibitors and other highly sophisticated medicines, many considered AIDS to be invariably fatal. While I am not in a position to speak about the specifics of these new medicines, their development has given new hope to many millions of people living with HIV.

This result is in part a tribute to patent protection, which has given pharmaceutical companies an incentive to research these and many other treatment options which may bear fruit in the future. It is our strong belief that international respect for intellectual property will be an important part of the solution to the crisis.

The foundation of the Administration's approach to patent protection is to ensure that the necessary incentives are provided to promote rapid innovation of new drug therapies and to ensure the protection of the medicines which now exist. The Administration cares deeply about the HIV/AIDS crisis, in Africa and elsewhere, and is active on a variety of fronts to combat this disease. On Monday of this week, the Vice President announced a new $100 million initiative to help fight AIDS in Africa. However, this Administration also supports international respect for intellectual property rights, in the belief that patent protection will ultimately be part of the

solution to the crisis.

First, patent protection is an essential policy to encourage rapid development of new and more effective drugs to treat AIDS. Together with government investment in research, private sector incentives for research and development are critical to develop new treatments for AIDS as well as other diseases. To effectively remove patent protection for such treatments would ultimately be to delay the discovery and production of medicines which could go beyond treatment to prevention and cure.

Second, while my colleagues from NIH and the CDC can speak to this directly, I understand that we are seeking to help developing countries create the public health infrastructure that will allow effective AIDS treatment. This includes not only adequate investment in prevention efforts, clinics and medical equipment, but continuous monitoring of treatments to ensure that no contamination occurs and that medicines are provided at the time and with the dosage recommended by their manufacturers. The Vice President's Monday announcement is an important component of this.

Without such infrastructure, there is risk that pharmaceuticals, including antibiotics and HIV drugs, will not be administered to patients correctly. This poses risks not only to individual patients but the wider community, as without proper administration bacteria and viruses will mutate, creating powerful new forms of drug-resistant organisms.

THE SOUTH AFRICAN CASE

And this brings me to the specific case of South Africa.

We appreciate that the government of South Africa has undertaken to improve access to quality health care for its people. This is a goal we fully endorse and support. We believe that this goal can be achieved while promoting adequate and effective patent protection for pharmaceutical products. Our goal is to chart a course that assists in improving access to affordable medicines, while not freezing the financial incentives that fuel continued research and production of new drugs. With a shared commitment to improve health care and provide intellectual property protection we are continuing our efforts to find common ground on our differences.

That said, we have concerns about South Africa's new Medicines Act, which we are working hard to resolve. For example, this Act appears to grant the Health Minister ill-defined authority to issue compulsory licenses, authorize parallel imports, and potentially otherwise undermine patent rights in a manner that may not be consistent with even the minimum standards set out in the WTO TRIPS Agreement or South Africa's other international obligations. We seek clarification from South Africa that Article 15(c) will be TRIPS-consistent.

The US Government does not generally support compulsory licensing. However, the TRIPS Agreement has specific rules that govern compulsory licensing, which are expressed in Article 31. The Agreement establishes specific conditions to permit unauthorized use under exceptional circumstances while guarding the interests of the patent holder. For example, a patent holder may be compelled to grant a license, but only on a case-by-case basis, normally only after the proposed user of the patent has been unable to obtain a license on a voluntary basis on reasonable commercial terms. This later requirement may be waived in a "national emergency." However, even in the case of such an emergency, other conditions apply, involving a requirement to pay "adequate remuneration" to the patent holder and to permit the licensing decision to be

subject to judicial review. Finally, the product should not be exported to a third country. The South African Medicines Act does not provide for any of these conditions.

FACT SHEET: HIV/AIDS IN AFRICA

Scope of Crisis

Of the 33 million people living with HIV/AIDS worldwide, 22 million – or 2/3 – live in sub-Saharan Africa. AIDS is now the number one cause of death in Africa, killing approximately 5,000 people per day, 175,000 per month – 1.9 million per year.

According to UNAIDS, one in five adults in Botswana, Namibia, Swaziland and Zimbabwe are infected. In South Africa alone, 3 million are HIV positive, and it is estimated that 1,500 new infections occur daily.

In some countries in Africa, it is predicted that life expectancy will fall by up to 1/3 in the next 10 years due to AIDS. And by the year 2010, USAID estimates that there will be 40 million AIDS orphans worldwide – more than ½ of them in Africa.

In a recent article, The Economist estimated that South Africa – the most robust economy in sub-Saharan Africa – has a reduction in its GDP by nearly 1% per year due to AIDS.

What the U.S. is doing to respond

The U.S. is the world's leading donor for the prevention and control of HIV/AIDS in the developing world. In FY99 USAID will spend $125 million worldwide on HIV/AIDS prevention and control, $74 million of that in Africa.

Since 1986, USAID has committed nearly $1 billion worldwide on programs aimed at prevention of HIV/AIDS and other sexually transmitted diseases. In FY98 USAID also launched a new $50 million initiative against infectious diseases, including HIV/AIDS, laying a foundation in Africa, Asia and Latin America for a global effort to combat infectious diseases.

Our international programs primarily are aimed at combating heterosexual transmission (the most common means of transmission in the developing world). Programs focus on education, changing high risk behavior, promoting condom use, controlling other sexually transmitted diseases, improving the policy environment to reduce transmission of HIV, conducting research and promoting advocacy, monitoring and evaluation, care and support activities, including community-based orphan care and voluntary counseling and testing programs.

Although the U.S. is spending $200 million this year alone on the development of a vaccine, we are a long way from having an effective product. And while new anti-HIV drugs dramatically improve and extend life, they are not a cure. Prevention based on behavior change remains the primary intervention at this time.

HIV/AIDS

- The United States government, particularly the President, the First Lady and the Vice President have taken an active role in publicizing the AIDS crisis in Africa, and in ensuring that the U.S. strongly supports African efforts to combat the disease. As a matter of fact, the Vice President and then-Deputy President Mbeki highlighted the HIV/AIDS crisis during the Vice President's last visit to South Africa in February.

- This Administration has done more than any previous Administration to fight the scourge of HIV/AIDS both here at home and abroad. We have accomplished much, but much more still needs to be done.

- This is especially important as 70% (23 million) of the 33 million people living with HIV/AIDS live in sub-Saharan Africa, and 12 million out of the 14 million deaths (83%) caused by HIV/AIDS have occurred in sub-Saharan Africa.

- The U.S. is by far the world's leading donor for the prevention and control of HIV/AIDS in the developing world. This year (FY99) USAID will spend $125 million worldwide on HIV/AIDS prevention and control, $74 million of that in sub-Saharan Africa - including $7 million alone for AIDS orphans and infected children.

- This is a continuation of our long-term efforts. Since 1986, the United States has funded HIV/AIDS education, treatment, and prevention programs across Africa, spending nearly $1 billion on these programs, reaching people in 38 countries in sub-Saharan Africa.

- The United States continues to be a leading donor in the fight against HIV/AIDS in some of the worst hit countries on the continent. For example, from 1986-1998, through USAID funding, the U.S. government contributed over $46 million to fund counseling, testing, education, prevention, and treatment programs in Uganda. This is more than ¼ of the total donor contributions to Uganda's aggressive and successful effort – the only example outside of Thailand in the developing world – to halt the increase in HIV infection rates.

- Our international programs primarily are aimed at combating HIV transmission (more than 70% of infections worldwide are from heterosexual contact). Programs focus on education, changing high risk behavior, promoting condom use, controlling other sexually transmitted diseases, improving the policy environment to reduce transmission of HIV, conducting research and promoting advocacy, monitoring and evaluation, care and support activities, including community-based orphan care and voluntary counseling and testing programs.

- Although the U.S. is spending $200 million this year alone on the development of a vaccine, we are a long way from having an effective product. And while new anti-HIV drugs dramatically improve and extend life, they are not a cure. Prevention based on behavior change remains the primary intervention at this time.

South Africa/IPR issue:

- We applaud recent efforts by many of Africa's leaders, including those of President Mandela, South Africa's Deputy President Mbeki, Ghana's President Rawlings, Namibia's President Nujoma, and many others to publicize the dangers of HIV/AIDS and the need for a united and concerted effort by communities to prevent its further spread and support those already infected.

- In South Africa, we share a mutual goal with the government to bring better health care to the people of South Africa, including those suffering as a result of HIV/AIDS. We believe this goal can be achieved while promoting effective and adequate patent protections for pharmaceutical products. Our goal is to chart a course that assists in improving access to affordable medicines, while not freezing the financial incentives that fuel continued research and production of new drugs. With a shared commitment to improve health care and provide intellectual property protections we are continuing our efforts to find common ground on our differences.

- That said, we do have concerns with some provisions of South Africa's Medicines Act. The lack of definition in the Act makes it unclear whether it is compliant with TRIPs.

- The U.S. government does not generally support compulsory licensing, but the WTO TRIPs agreement does provide for the practice - a patent holder may be compelled to grant a license, but only on a case-by-case basis, normally only after the proper user of the patent has been unable to obtain a license on a voluntary basis on reasonable commercial terms. This requirement may be waived in a "national emergency" but in the case of an emergency, other conditions apply.

- While we do not believe that compromising IPR protections is the solution to the greater problems, contrary to our general approach, we raise no objection to compulsory licensing and parallel importation of pharmaceuticals by South Africa in response to their situation, as long as it is done in a way that is compliant with TRIPs.

- Globally we continue to have concerns about parallel importing both for reasons of safety and efficacy of drugs and for the possibility it presents for patent infringement. That said, this policy is consistent with our position on TRIPs.

- We continue to assist South Africa in addressing the AIDS crisis through a variety of means, including:
  - ✓ a $10 million five-year program to support the South African government and local NGOs efforts to fight HIV/AIDS.
  - ✓ work with the South African National Youth Commission, which has identified HIV/AIDS as a priority activity
  - ✓ ongoing discussions in our Binational Commission's Health Working Group on ways to enhance our cooperative efforts to fight AIDS, and
  - ✓ expanding available resources through public-private partnerships

- This position is consistent with U.S. policy.
- It is also responsive to the raging health crisis in South Africa.

HIV/AIDS Crisis in Africa and U.S. Response

The U.S. is accused by Ralph Nader and others of preventing access to medicines to combat HIV/AIDS in Africa. Mr. Nader states that U.S. – and specifically the Vice President's - support for pharmaceutical companies' complaints against the South African Government's efforts to make drugs more affordable has deprived thousands of needed treatments. What is your response to this?

- The United States government, particularly the President, the First Lady and the Vice President have taken an active role in publicizing the AIDS crisis in Africa, and in ensuring that the U.S. strongly supports African efforts to combat the disease.

- This Administration has done more than any previous Administration to fight the scourge of HIV/AIDS both here at home and abroad. We have accomplished much, but much more still needs to be done.

- This is especially important as 70% of the 34 million people living with HIV/AIDS live in sub-Saharan Africa, and 11.5 million out of the 14 million deaths caused by HIV/AIDS have occurred in sub-Saharan Africa. Since 1986, the United States has spent $ ____ million to control the spread of HIV/AIDS. More than 50% of those funds have been dedicated to sub-Saharan Africa. Since the early 1990s, the U.S. has been the lead donor to the UNAIDS Program, contributing more than 25% of the budget and 48% of overall development assistance devoted to HIV care and prevention in the developing world.

- This year the United States will spend $76 million to combat HIV/AIDS in sub-Saharan Africa, including $7 million alone for AIDS orphans and infected children. This represents a trebling of our assistance since 1992.

- We applaud recent efforts by many of Africa's leaders, including those of President Mandela, South Africa's Deputy President Mbeki, Ghana's President Rawlings, Namibia's President Nujoma, Zambia's President Chiluba and many others to publicize the dangers of HIV/AIDS and the need for a united and concerted effort by communities to prevent its further spread and support those already infected.

- In South Africa, we share a mutual goal with the government to bring better health care to the people of South Africa, including those suffering as a result of HIV/AIDS. We believe this goal can be achieved while promoting effective and adequate patent protections for pharmaceutical products. With a shared commitment to improve health care and provide intellectual property protections we are continuing our efforts to find common ground on our differences.

- That said, we do have concerns with provisions of South Africa's Medicines Act, which may grant the Minister of Health broad discretion to authorize parallel importing of pharmaceutical products in a manner inconsistent with international trade agreements. The lack of definition provided in the Act may also grant authority to undermine other patent rights with respect to pharmaceuticals.

- We believe that commercial incentives to market pharmaceutical products are necessary, if we expect private industry to support continued research and the introduction of new, more effective pharmaceuticals. We will continue to work with the AIDS community and people living with AIDS both here and abroad to find ways to expand access to treatment. We will also continue to work in a sense of partnership with the South African government to resolve our outstanding differences related to intellectual property rights protections and the Medicines Act.

- The United States continues to be a leading donor in the fight against HIV/AIDS in some of the worst hit countries on the continent. For example, from 1986-1998, through USAID funding, the U.S. government contributed over $46 million to fund counseling, testing, education, prevention, and treatment programs in Uganda. This is more than ¼ of the total donor contributions to Uganda's aggressive and successful effort to slow the increase in HIV infection rates.

- In South Africa, the United States, through USAID recently committed to fund a $10 million five-year program to support the South African government and local NGOs efforts to fight HIV/AIDS. We are seeking to expand these resources through public-private partnerships.