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**OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE
EXECUTIVE OFFICE OF THE PRESIDENT
WASHINGTON, D.C.
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**FOR IMMEDIATE RELEASE
December 1, 1999**

**99-98
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THE PROTECTION OF INTELLECTUAL PROPERTY AND HEALTH POLICY

United States Trade Representative Charlene Barshefsky and Health and Human Services Secretary Donna E. Shalala today announced their intention to develop a cooperative approach on health-related intellectual property matters to ensure that the application of U.S. trade law related to intellectual property remains sufficiently flexible to respond to ~~legitimate~~ public health crises. In addition, Ambassador Barshefsky announced the removal of the Republic of South Africa from the special 301 "watch list."

"Recent developments in AIDS treatments give us all hope for helping those already living with HIV and for preventing new infections by interrupting maternal to child transmission. The challenge of making treatments a viable option for those who need them is one that eludes simple answers" said Secretary Shalala. "The United States will continue to work with its partner nations, multilateral organizations, industry, and affected communities to improve access to treatment."

"A modern patent system helps promote the rapid innovation, development, and commercialization of effective and safe drug therapies - therapies such as those now being deployed in the war against HIV/AIDS" said Ambassador Barshefsky. "Secretary Shalala and I believe that sound public health policy and intellectual property protection are, and must continue to be, mutually supportive."

Recognizing that health emergencies may require special measures, USTR and HHS are working together to establish a process for analyzing and evaluating health issues that arise in the application of U.S. trade-related intellectual property law and policy. When a foreign government expresses concern that U.S. trade law related to intellectual property significantly impedes its ability to address a health crisis in that country, USTR will seek and give full weight to the ~~advice~~ of HHS regarding the health considerations involved. This process will permit the

*to the information
provided by*

application of U.S. trade-related intellectual property law to remain sufficiently flexible to react to public health crises brought to the attention of USTR. It will also ensure that the minimum standards of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) are respected.

TRIPS provides minimum standards for protecting intellectual property rights. For example, TRIPS requires WTO members to grant time-limited exclusive rights through patents, while permitting use without the authorization of the right holder (e.g., compulsory licensing) under certain limited circumstances and conditions. The provisions of the TRIPS Agreement are being phased-in over time. January 1, 2000, is an important implementation date for developing countries. The Agreement takes special note of the least-developed countries; obligations on these countries generally do not apply until 2006.

Ambassador Barshefsky also announced that she is removing South Africa from the special 301 "watch list." The recent bilateral understanding developed with South Africa illustrates the complementary nature of sound public health and intellectual property policies. Under the September 17, 1999, understanding, both Governments reaffirmed their shared objective of fully protecting intellectual property rights under the WTO TRIPS Agreement, while addressing the health issues identified by South Africa. South Africa agreed that it would address health needs in a manner that fully protects intellectual property rights. Ambassador Barshefsky took this action as a result of this understanding, as well as other steps South Africa has and is taking to improve further the protection of intellectual property.

**PRESIDENT CLINTON ANNOUNCES NEW COOPERATIVE EFFORT TO
HELP POOR COUNTRIES GAIN ACCESS TO AFFORDABLE MEDICINES,
INCLUDING FOR HIV/AIDS TREATMENT**

December 1, 1999

The President today announced that the Office of the United States Trade Representative (USTR) and the Department of Health and Human Services (HHS) will develop a cooperative approach on health-related intellectual property matters consistent with our goal of helping poor countries gain access to affordable medicines. Through this approach, we will ensure the application of U.S. trade law related to intellectual property remains sufficiently flexible to respond to legitimate public health crises. President Clinton also called upon our trading partners to join him in this effort. The United States will continue to work with its partner nations, multilateral organizations, industry, and affected communities to improve access to treatment.

Poor countries face special challenges providing adequate public health care and gaining access to affordable medicines, including those needed to treat diseases such as HIV/AIDS.

- Under this new arrangement there will be a more direct interaction between USTR and HHS on health-related intellectual property issues.
- When a foreign government expresses concern that the application of U.S. trade law related to intellectual property significantly impedes its ability to address a health crisis, USTR will seek substantive information from HHS on the health conditions prevailing in that country.
- This will enable USTR to ensure that the application of U.S. trade law related to intellectual property, consistent with international trade treaties, is sufficiently flexible to respond to public health crises.

The challenge of improving access to treatments without stifling innovation is one that eludes simple answers. A modern patent system helps promote the rapid innovation, development, and commercialization of effective and safe drug therapies for diseases such as HIV/AIDS. Sound public health policy and intellectual property protection are, and must continue to be, mutually supportive. The WTO Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) allows the flexibility for all WTO Members to respond to public health crises.

As a related policy objective, we continue to assist developing countries create the public health infrastructure that will allow treatments to be utilized effectively. Treating diseases effectively requires that developing countries not only make adequate investment in prevention efforts, clinics and medical equipment, but continuous monitoring of treatments to ensure that no contamination occurs and that medicines are administered at the time and with the appropriate dosage. Without such infrastructure, there is significant risk that pharmaceuticals, including antibiotics and HIV drugs, may not be administered to patients correctly.

**Heath and Trade Announcement
December 1, 1999**

Question: What are the implications of the agreement between USTR and HHS?

Answer:

- Under this new arrangement there will be a more directed interaction between USTR and HHS on health-related intellectual property issues.
- When a foreign government expresses concern that U.S. trade law related to intellectual property significantly impedes its ability to address a health crisis, USTR will seek substantive information from HHS on the health conditions prevailing in that country.
- This will enable USTR to ensure that the application of U.S. trade law related to intellectual property, consistent with international trade treaties, is sufficiently flexible to respond to legitimate public health crises.

Question: Does this mean USTR is globalizing its recent understanding with South Africa?

- Through consultations with HHS, USTR will ensure that the unique health demands of individual nations are given careful consideration in the application of U.S. trade law.
- We will make this determination on a case by case basis after a thorough analysis of each individual situation once a foreign government has expressed concerns to us.

Question: What was the understanding with South Africa?

- Under the understanding both governments reaffirmed their shared objective of fully protecting intellectual property rights under the WTO TRIPS Agreement, while addressing the health issues identified by South Africa. South Africa agreed that it would address health needs in a manner that fully protects intellectual property rights.

(If Asked)

- This means that if South Africa engages in compulsory licensing or parallel importing, inter alia, it will do so consistent with existing international obligations.

Question: What is the Administration's response to claims that the TRIPS Agreement should be amended because it conflicts with developing countries efforts to address health issues?

- TRIPS does not interfere with health policy. In fact, HHS and USTR agree that sound public health policy and intellectual property protection are mutually supportive.

- As seen in the case of South Africa, TRIPS allows the flexibility for developing countries to respond to public health crises.
- Without IP protection, the incentive to create innovative new drugs is seriously threatened.
- Many countries that are facing health crises do not offer patent protection for pharmaceuticals, therefore patent protection can hardly be the cause of the problem.

Question: What is the U.S. view of proposals to patents on drugs designated by the WHO as essential drugs?

- We oppose proposals to deny patents on drugs designated by the WHO as essential. The vast majority of the drugs designated as essential by the WHO are not under patent anywhere in the world. ~~Clearly, patent protection is not standing in the way of access to these essential drugs.~~
- Senior officials at the WHO do not support this proposal and do not feel it would have any positive impact on access to essential drugs.

(If Raised),

Question: What is the U.S. view of the proposal recently made by the EU, Korea, Japan and others relating to compulsory licensing for WHO essential drugs.

- We have only recently become aware of this proposal and are still studying it.
- We would point out that the TRIPS agreement already allows WTO members to issue compulsory licenses under certain conditions.
- In addition, we understand that the majority of the drugs on the WHO's list of essential drugs are not under patent anywhere in the world.

Question: We understand the Thai Government is under pressure to issue compulsory licenses on HIV drugs such as DDI.

- The Thai Government has not approached us about the situation you describe. If the Thai Government does indeed approach us on this issue, USTR will certainly consult closely with them and with HHS before determining the best course of action.

Question: Isn't it true that the USG imposed trade sanctions on Thailand in 1998 because it attempted reduce the costs of medicines?

- Recently there have been articles stating that Thailand enacted a patent law in 1992 in response to U.S. threats to restrict trade preferences.

- In fact, in 1993 the USG restored certain trade preferences to Thailand that had been revoked in 1988, pursuant to U.S. trade law, over concerns about the lack of intellectual property protection in Thailand
- It is important to note that the 1998 "IPR action plan" and restoration of certain benefits was the USG's attempt to focus the Thai government's attention on the growing copyright piracy problem and to promote cooperation between our government to improve IPR protection.

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Sandy, attached is the draft USTR/HHS press release. As we discussed, I'd appreciate it if you did not share this outside the government before the event. I spoke with Tom Novotny at HHS today and he will call you on Monday. Claude Burcky and I will be in Seattle next week and will be staying at the Madison Renaissance (206) 583-0300. We should also be reachable on Internet e-mail jpapovich@ustr.gov and cburcky@ustr.gov. If cell phones will be working in Seattle, Claude can be reached at 202-329-7289.

Press Release on USTR Letterhead

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GENERAL SERVICES ADMINISTRATION

FOR IMMEDIATE RELEASE
SEPTEMBER 17, 1999

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99-76

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HELAINE KLASKY

AMY STILLWELL

U.S. - South Africa Understanding on Intellectual Property

United States Trade Representative Charlene Barshefsky today announced that the Governments of the United States and South Africa have come to an understanding with respect to South Africa's urgent need to provide better, more affordable health care while ensuring that intellectual property rights are protected. This understanding was reached working through the mechanism of the Council of the Trade and Investment Framework Agreement (TIFA).

"The Government of South Africa is battling a very serious AIDS pandemic," stated Ambassador Barshefsky. "The United States Government fully supports President Mbeki and his Government in their effort to combat this problem and is committed to do whatever it can to help.

Both Governments also have reaffirmed their shared objective of fully protecting intellectual property rights, including their commitment to comply with the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement). They recognized that this Agreement is designed to ensure high levels of intellectual property protection while enabling governments to address national social needs.

Between these shared commitments, the two governments have identified common ground with respect to South Africa's implementation of its so-called "Medicines Act." "The United States very much appreciates South Africa's assurance that, as it moves vigorously forward to bring improved health care to its citizens, it will do so in a manner consistent with international commitments and that fully protects intellectual property rights," continued Ambassador

DRAFT
JOINT STATEMENT BETWEEN THE GOVERNMENTS OF SOUTH AFRICA AND
THE UNITED STATES OF AMERICA
17 September 1999

Over the past few months, officials of the Governments of South Africa and the United States of America have been exchanging views with the aim of reaching a common understanding on the matter of intellectual property as it pertains to the pharmaceutical industry.

We are pleased to announce that a resolution to this matter has now been found. This is premised on the commitment of both Governments to Agreement on Trade Related Intellectual Property Rights (TRIPS), under the auspices of the World Trade Organization, as well as an appreciation of the South African Government's efforts to provide affordable health care to its people.

It is the express position of the South African Government that, in the implementation of the provisions of the Medicines Act - which permits parallel importation and compulsory licensing of patents for pharmaceuticals - it will honour its obligations under the TRIPS Agreement.

We strongly welcome the fact that this matter has been clarified to the satisfaction of both Governments. Indeed, our two countries can now move forward to strengthen our co-operation on matters of common interest, without the distraction that this issue had become.

The Governments of the United States of America and South Africa hope that the resolution of this matter will open the way for South Africa to pursue its much-needed health reforms in the interests of its people.