

FOIA MARKER

This is not a textual record. This is used as an administrative marker by the Clinton Presidential Library Staff.

Folder Title:

HIV-AIDS IPR [Intellectual Property Rights]

Staff Office-Individual:

National Economic Council-Brainard, Lael

Original OA/ID Number:

CF 1360

Row:	Section:	Shelf:	Position:	Stack:
23	5	1	1	V

IPR BACKGROUND

FAX COVER SHEET



Transmit # _____

Time Sent: _____

Initials: _____

Date: 5/4/00Total Pages Sent: 8**Office of Services, Investment and Intellectual Property**

To: NAME	AGENCY	PHONE	FAX
<u>Lael Brannard</u>	<u>NEE</u>	<u>65333</u>	<u>62223</u>
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

From: Claude Burcky -WSTR (Section 19)
Phone: 395-6864 Return Fax: (202) 395-3891

If you have any problems receiving this fax call (202) 395-4510

Subject: Dec 1 & May 1 materials you requested.

03/04/00 THE 02:07 FAX 002

**OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE
EXECUTIVE OFFICE OF THE PRESIDENT
WASHINGTON, D.C.
20508**

USTR PRESS RELEASES ARE AVAILABLE ON THE USTR HOME PAGE AT WWW.USTR.GOV.
THEY ARE ALSO AVAILABLE THROUGH THE USTR FAX RETRIEVAL SYSTEM AT 202-395-4809.

**FOR IMMEDIATE RELEASE
December 1, 1999**

**99-97
CONTACT: THOMAS TRIPP
HELAINE KLASKY
AMY STILWELL
(202) 395-3230**

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 crisis. 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 application of U.S. trade-related intellectual property law to remain sufficiently flexible to react to public health

crisis 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, such as Special 301, 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 medical 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 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.

[[Return to WTO Conference Page](#)]



2000 SPECIAL 301 REPORT

United States Trade Representative Charlene Barshefsky today announced the results of the 2000 "Special 301" annual review which examined in detail the adequacy and effectiveness of intellectual property protection in over 70 countries. Ambassador Barshefsky also announced that, as a result of this year's Special 301 review, she will initiate World Trade Organization (WTO) dispute settlement consultations with Argentina and Brazil, and take the next step in our dispute with Denmark and request the establishment of a WTO panel unless imminent progress is made. This brings to 14 the number of intellectual property-related WTO complaints filed by the United States since 1996. Consultations about implementation of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) also may be initiated with other countries in the near future. The Special 301 report also addresses significant concerns in such trading partners as Ukraine, Italy, Israel, Malaysia, India, Korea, Poland, and the West Bank and Gaza, as well as progress in economies such as UAE, Sweden, Mexico, and Macau.

In this year's review, USTR devoted special attention to proper and timely implementation of the WTO TRIPS Agreement by developing country WTO members, which was required as of January 1, 2000. In addition, USTR continued to focus on two other critically important issues: cracking down on production of unauthorized copies of "optical media" such as CDs, VCDs, DVDs, and CD-ROMs, and ensuring that government ministries use only authorized software. Considerable progress has been made over the past year by many developing countries in implementing their TRIPS obligations. USTR also has made progress again this year in encouraging our trading partners to implement optical media controls and appropriate software management programs. While progress also has been made on improving enforcement in many countries, the unacceptably high rates of piracy and counterfeiting of U.S. intellectual property around the world require on-going vigilance.

2000 Special 301 Decisions

Under the Special 301 provisions of the Trade Act of 1974, as amended, Ambassador Barshefsky today identified 59 trading partners that deny adequate and effective protection of intellectual property or deny fair and equitable market access to United States artists and industries that rely upon intellectual property protection.

In today's action, the United States Trade Representative identified Ukraine for potential Priority Foreign Country designation on August 1, 2000. Ambassador Barshefsky stated that the United States has worked with Ukrainian officials over the past several years in an effort to reduce alarming levels of copyright piracy and to improve Ukraine's overall intellectual property regime. Regrettably, according to estimates from our copyright industry, Ukraine is the single largest source of pirate CDs in the Central and East European region. The U.S. Government currently is engaged with the Government of Ukraine in an intense effort to resolve this problem. At this juncture, the United States considers its interests to be best served by continuing these efforts

over the next few months. However, Ukraine will be identified as a Priority Foreign Country if it fails to make substantial progress toward eliminating pirate optical media production prior to August 1, 2000.

Copyright piracy in Ukraine is extensive and enforcement is severely lacking, resulting in increasing unauthorized production and export of CDs and CD-ROMs. U.S. industry estimates that losses to the music industry alone are \$210 million. The United States urges the Government of Ukraine to take stronger measures on an urgent basis to address this problem through the implementation of effective optical media production controls and other available means. In addition, a number of Ukraine's intellectual property laws, especially trademark, patent and copyright, fall short of compliance with the minimum standards set out in the TRIPS Agreement and the 1992 U.S.-Ukraine bilateral trade agreement. It is unclear whether Ukraine protects pre-1973 copyrighted works; it does not provide retroactive protection for sound recordings.

Ambassador Barshefsky again designated Paraguay and China for "Section 306 monitoring" to ensure both countries comply with the commitments made to the United States under bilateral intellectual property agreements. Special concern was expressed that Paraguay's efforts have not been sufficient in recent months, and further consultations will be scheduled.

Ambassador Barshefsky also announced placement of 16 trading partners on the "Priority Watch List": Argentina, the Dominican Republic, Egypt, the European Union, Greece, Guatemala, India, Israel, Italy, Korea, Malaysia, Peru, Poland, Russia, Turkey, and Ukraine. She also placed 9 trading partners on the "Watch List." Countries that were not mentioned in the report last year but are on the Watch List this year include: Armenia, Azerbaijan, Kazakhstan, Latvia, Lithuania, Moldova, Tajikistan, Turkmenistan, and Uzbekistan. In addition, out-of-cycle reviews will be conducted of Italy, Korea and Macau.

Finally, Ambassador Barshefsky noted that while she was not listing El Salvador or the West Bank and Gaza, USTR will conduct out-of-cycle reviews of each in September and December 2000, respectively. The review of El Salvador will assess the government's efforts to improve enforcement procedures and to promote the use of authorized software in all government ministries. The review of the West Bank and Gaza will assess its progress toward implementation of promised enforcement actions against pirate CD manufacturers.

Intellectual Property and Health Policy

On December 1, 1999, President Clinton announced that the United States is committed to helping developing countries gain access to essential medicines, including those for HIV/AIDS. Also on December 1, United States Trade Representative Charlene Barshefsky and Secretary of Health and Human Services Donna E. Shalala 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 public health

crises.

Specifically, the announcement stated that USTR and HHS will work together to establish a process for analyzing and evaluating health issues that are relevant to the application of U.S. trade-related intellectual property laws and policy. When a foreign government expresses concern that U.S. trade law related to intellectual property protection 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 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 TRIPS Agreement are respected.

In announcing the results of the Special 301 review today, Ambassador Barshefsky stated that USTR has begun implementation of the policy she and Secretary Shalala announced on December 1. USTR and HHS have done so by establishing a regular consultative mechanism on health-related intellectual property matters consistent with their goal of helping poor countries gain access to essential medicines. The agencies are also working closely with interested NGOs and industry to ensure that this policy is implemented effectively.

Since December 1, USTR and HHS staff have worked together to address individual health-related intellectual property issues that have arisen with U.S. trading partners, as in the case of Thailand, as well as with respect to the health-related issues that have arisen in this year's Special 301 process. For the first time, HHS has participated actively as a member of the Special 301 Trade Policy Staff Sub-Committee that is charged with developing the Special 301 recommendations. Ambassador Barshefsky said that she was very pleased to have been able to rely on the helpful support of HHS in making her final decisions in this review.

The Special 301 committee has not been approached directly by any government with a request under the December 1 policy. Nevertheless, the committee has taken health and development issues into account in accordance with the Administration's December 1 policy in making its Special 301 recommendations.

Ambassador Barshefsky went on to say that since December 1, USTR has encouraged U.S. trading partners facing a health care crisis to explore all options for extending access to effective treatments. Nevertheless, the U.S. Government has made clear that the final choice of what policies to employ is one for each government to make on its own. In the view of the U.S. Government, should a government determine to avail itself of the flexibility the TRIPS Agreement provides to address a health care crisis, the United States will raise no objection, provided the policy employed is consistent with the provisions of the WTO TRIPS Agreement.

Ambassador Barshefsky went on to stress that access to modern pharmaceuticals can and should be enhanced in a manner that assures the safety and efficacy of the drugs, preserves intellectual property rights, and promotes the worldwide pursuit of newer, more effective medicines. She

concluded by noting that a modern patent system helps promote the rapid innovation, development, and commercialization of effective and safe drug therapies and that sound public health policy and intellectual property protection are mutually supportive.

Implementation of the WTO TRIPS Agreement

One of the most significant achievements of the Uruguay Round was negotiation of the TRIPS Agreement, which requires all WTO Members to provide certain minimum standards of protection for patents, copyrights, trademarks, trade secrets, and other forms of intellectual property. The Agreement also requires countries to provide effective enforcement of these rights. In addition, the TRIPS Agreement is the first broadly-subscribed multilateral intellectual property agreement that is enforceable between governments, allowing them to resolve disputes through the WTO's dispute settlement mechanism.

While developed countries are already required to fully implement TRIPS, developing countries were given a five year transition period -- until January 1, 2000 -- to implement most of the Agreement's provisions. Ensuring that developing countries are in full compliance with the Agreement now that this transition period has come to an end is one of this Administration's highest priorities with respect to intellectual property rights. With respect to least developed developing countries, and with respect to the protection of pharmaceuticals and agriculture chemicals in certain developing countries, an even longer transition was provided.

Substantial progress has been made over the past year by developing countries toward full implementation of their TRIPS obligations. The United States has worked diligently to assist countries in meeting this goal through consultations and bilateral technical assistance.

Nevertheless, a review of developing country implementation, launched last December, has revealed that a number of countries are still in the process of finalizing implementing legislation. The United States will continue to work with such countries and expects further progress in the very near future to complete this process. However, in those instances where additional progress is not likely in the near term, or where the United States has been unable to resolve concerns through bilateral consultation, we are pursuing our rights through WTO dispute settlement proceedings.

Ambassador Barshefsky stated that she is today announcing initiation of dispute settlement proceedings to address significant deficiencies in Argentina's patent regime. USTR also is initiating consultations with Brazil to address a longstanding difference between our two governments with respect to a narrow aspect of Brazil's patent regime.

The United States has had longstanding concerns with Argentina's implementation of its obligations in the area of intellectual property protection, including for pharmaceuticals and agricultural chemicals. In fact, at this time last year the United States invoked its WTO rights because of Argentina's failure to comply with its TRIPS Agreement obligations which came into