

## 2003 SPECIAL 301 REPORT

### Executive Summary

United States Trade Representative Robert B. Zoellick today announced the results of the 2003 "Special 301" annual review, which examined in detail the adequacy and effectiveness of intellectual property protection in approximately 74 countries.

USTR notes with disappointment Ukraine's persistent failure to take effective action against significant levels of optical media piracy and to implement intellectual property laws that provide adequate and effective protection. As a result, Ukraine will continue to be designated a Priority Foreign Country and the \$75 million worth of sanctions imposed on Ukrainian products on January 23, 2002 will remain in place. This continued failure to adequately protect intellectual property rights could also jeopardize Ukraine's efforts to join the World Trade Organization (WTO) and seriously undermine its efforts to attract trade and investment. The U.S. Government continues to remain actively engaged with Ukraine in encouraging the nation to combat piracy and to enact the necessary intellectual property rights legislation and regulations.

The Special 301 report addresses significant concerns with respect to such trading partners as Brazil, The Bahamas, Mexico, India, Indonesia, Korea, Lebanon, Taiwan, Poland, the Philippines, Russia, the European Union (EU), and members of the Andean Community. In addition, the report notes that the United States will consider all options, including but not limited to initiation of dispute settlement consultations with countries that do not appear to have implemented fully their obligations under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).

In this year's review, USTR devotes special attention to the growing issue of counterfeiting and piracy, with particular emphasis on the ongoing campaign to reduce production of unauthorized copies of "optical media" products such as CDs, VCDs, DVDs, and CD-ROMs. Counterfeiting of trademarked goods is an increasing problem in many countries, including China, Paraguay, Poland, the Philippines, Russia, Vietnam, and Turkey. In addition, USTR continues to focus on other critically important issues including internet piracy, proper implementation of the TRIPS Agreement by developing country WTO Members and full implementation of TRIPS standards by new WTO Members at the time of their accession. USTR also continues to encourage countries to ensure that government ministries use only authorized software.

Over the past year, many developing countries and newly acceding WTO Members made progress toward implementing TRIPS obligations. Nevertheless, full implementation of TRIPS obligations has yet to be achieved in certain countries, particularly with respect to the Agreement's enforcement provisions. As a result, piracy and counterfeiting of U.S. intellectual property remain unacceptably high in these countries.

The United States is committed to a policy of promoting increased intellectual property protection. In this regard, we are making progress in advancing the protection of these rights through a variety of mechanisms, including through the negotiation of free trade agreements. We are pleased that the recently concluded free trade agreements (FTAs) with Chile and Singapore will strengthen the protection of intellectual property rights in those two countries. Specifically, the intellectual property chapters of those two agreements provide for higher levels of intellectual property protection in a number of areas covered by the TRIPS Agreement. We are also seeking higher levels of protection and enforcement in the FTAs that are currently under negotiation with Central America, Morocco, Australia, and the Southern Africa Customs Union, and in the ongoing negotiation of a Free Trade Area of the Americas.

USTR will continue to use all statutory tools, as appropriate, to improve intellectual property protection in such countries where it is inadequate, such as Ukraine, Russia, Brazil, Peru, Ecuador, Bolivia, Venezuela, the Dominican Republic, Pakistan, Thailand and Turkey including through implementation of the Generalized System of Preferences and other trade preference programs.

### **Global Scourge of Counterfeiting and Piracy**

One area of particular concern in this year's report is counterfeiting and digital piracy, which has increased dramatically in recent years. Unfortunately, in the area of counterfeiting what was once a localized industry concentrated on the copying of high-end designer goods has now become a massive, sophisticated global business involving the manufacturing and sale of counterfeit versions of everything from soaps, shampoos, razors and batteries to cigarettes, alcoholic beverages and automobile parts, as well as medicines and health care products.

Counterfeiting of such a broad range of products on a global scale affects more than just the companies that produce legitimate products. While it has a direct impact on the sales and profits of those companies, counterfeits also hurt the consumers who waste their money and sometimes put themselves at risk by purchasing fake goods. It also hurts the countries concerned, by decreasing tax revenues and deterring investments. In addition, counterfeiters pay no taxes or duties and do not comply with basic manufacturing standards for the health and safety of workers or product quality and performance.

Piracy and counterfeiting of copyrighted products in digital format, as well as counterfeiting of all types of trademarked products, has grown to such a scale because it offers enormous profits and little risk for the criminal element of society. Criminals can get into the counterfeiting business with little capital investment, and even if caught and charged with a crime, the penalties in many countries are so low that they offer no deterrent. This is why USTR seeks through our FTAs, and through our bilateral consultations to ensure that criminal penalties are high enough to have a deterrent effect, as well as to ensure that pirated and counterfeit products, and the

equipment used to make them, are seized and destroyed. These products can be produced and sold at prices much lower than legitimate products, but still deliver attractive profit margins for the infringer because the counterfeit and pirated products are usually made with substandard materials, and undergo little or no quality control or even basic health and safety testing. The economic damage caused by counterfeiting to the legitimate companies whose products are counterfeited is enormous. Losses to U.S. industries alone are estimated at \$200 to \$250 billion per year.

### **Controlling Optical Media Production**

To address existing and prevent future piratical activity, over the past year some of our trading partners, such as Malaysia and Taiwan, have taken important steps toward implementing, or have committed to adopt, much needed controls on optical media production. We await news of aggressive enforcement of these laws. However, others that are in urgent need of such controls, including Ukraine, Thailand, Indonesia, Pakistan, the Philippines, and Russia, have not made sufficient progress in this regard.

Governments such as those of China, Hong Kong, and Macau that implemented optical media controls in previous years have clearly demonstrated their commitment to continue to enforce these measures. The effectiveness of such measures is underscored by the direct experience of these governments in successfully reducing pirate production of optical media. We continue to urge our trading partners facing the threat of pirate optical media production within their borders to adopt similar controls or aggressively enforce existing regulations in the coming year. USTR is concerned, moreover, about recent reports of increased piracy and counterfeiting in Bulgaria, which had been a model in its region for taking the necessary steps to tackle optical media piracy by, for example, enacting optical media controls. Particularly troubling are reports that the CD plant licensing laws may be revised in a manner that would undermine, not improve, their effectiveness. We will be closely monitoring the situation and look to the Government of Bulgaria to maintain strong optical disk regulations.

### **Implementation of the WTO TRIPS Agreement**

One of the most significant achievements of the Uruguay Round was the negotiation of the TRIPS Agreement, which requires all WTO Members to provide certain minimum standards of protection for patents, copyrights, trademarks, trade secrets, geographical indications and other forms of intellectual property. The Agreement also requires countries to provide effective enforcement of these rights. 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.

Developed countries were required to fully implement TRIPS as of January 1, 1996, while developing countries were given a transition period – until January 1, 2000. 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 countries, and with respect to the protection of pharmaceuticals and agriculture chemicals in certain developing countries, even longer transitions are provided.

Progress continues to be made by developing countries toward full implementation of their TRIPS obligations. Nevertheless, certain countries are still in the process of finalizing implementing legislation and establishing adequate enforcement mechanisms. Every year the U.S. Government provides extensive technical assistance and training on the implementation of the TRIPS Agreement, as well as other international intellectual property agreements, to a large number of U.S. trading partners. Such assistance is provided by a number of U.S. Government agencies, including the U.S. Patent and Trademark Office, the U.S. Copyright Office, the State Department, the U.S. Customs Service, and the Justice Department, on a country-by-country basis, as well as in group seminars, including those co-sponsored with WIPO and the WTO. Technical assistance involves review of, and drafting assistance on, laws concerning intellectual property and enforcement. Training programs usually cover the substantive provisions of the TRIPS Agreement, as well as enforcement. The United States will continue to work with WTO Members and expects further progress in the near term to complete the TRIPS implementation process. However, in those instances where additional progress is not achieved in the near term, the United States will pursue our rights through WTO dispute settlement proceedings.

One the key implementation priority that we have focused on in this review is the implementation of Article 39.3, which requires WTO Members to protect test data submitted by drug companies to health authorities<sup>1</sup> against disclosure of that data and against "unfair commercial use" of that data.

Most countries, including the United States, impose stringent regulatory testing requirements on companies seeking to market a new drug or agricultural chemical product. Many countries have recognized, however, the value of allowing abbreviated approval procedures for second-comers seeking to market an identical product to one that has already been approved. Generally, these second applicants may be required to demonstrate only the bioequivalence of their products with the product of the first company, and will not be required to repeat all of the expensive and laborious clinical tests conducted by the first company to prove the safety of the product.

However, because of the expense involved in producing the safety and efficacy data needed to obtain marketing approval, the TRIPS Agreement recognizes that the original applicant should be entitled to a period of exclusivity during which second-comers may not rely on the data that

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<sup>1</sup> Such data is typically required by authorities in order to establish the safety and efficacy of a drug, and obtain government approval to market the drug.

the innovative company has created to obtain approval for their copies of the product. During this period of exclusive use, the data cannot be relied upon by regulatory officials to approve similar products. This period of exclusivity is generally five years in the United States and six to ten years in the EC member States. Other countries that provide a period of exclusivity against reliance on data include Australia, Canada, China, Czech Republic, Estonia, Japan, Jordan, Korea, Mexico, New Zealand, Slovenia, and Switzerland. We commend Hungary and Colombia on their recently implemented decrees that provide data protection. We urge all WTO members to swiftly complete their implementation of Article 39.3 including the rest of the countries in the Andean Community, as well as Israel.

### **Internet Piracy and the WIPO Copyright Treaties**

Throughout the world, countries have begun to recognize the importance of the Internet as a vehicle for economic expansion. However, despite the promise that the Internet holds for innovative and creative industries, it also creates significant challenges, as it serves as an extremely efficient global distribution network for pirate products. We are currently working with other governments, and consulting with U.S. industry, to develop the best strategy to address Internet piracy.

An important first step in the fight against Internet piracy was achieved at the World Intellectual Property Organization (WIPO) when it concluded two copyright treaties in 1996: the WIPO Copyright Treaty (WCT) and the WIPO Performances and Phonograms Treaty (WPPT), referred to as the WIPO Internet Treaties. These treaties help raise the minimum standards of intellectual property protection around the world, particularly with respect to Internet-based delivery of copyrighted works. They clarify exclusive rights in the on-line environment and specifically prohibit the devices and services intended to circumvent technological protection measures for copyrighted works. Both treaties entered into force in 2002.

These treaties represent the consensus view of the world community that the vital framework of protection under existing agreements, including the TRIPS Agreement, should be supplemented to eliminate any remaining gaps in copyright protection on the Internet that could impede the development of electronic commerce.

In order to realize the enormous potential of the Internet, a growing number of countries are implementing the WIPO Internet Treaties and creating a legal environment conducive to investment and growth in Internet-related businesses and technologies. In the competition for foreign direct investment, these countries now hold a decided advantage. We urge other governments to ratify and implement the two WIPO Internet Treaties.

## **Other Initiatives Regarding Internet Piracy**

We are seeking to incorporate the highest standards of protection for intellectual property into appropriate bilateral and regional trade agreements that we negotiate. We had our first success in this effort by incorporating the standards of the WIPO Internet Treaties as substantive obligations in our FTA with Jordan. The Jordan FTA laid the foundation for pursuing this goal in the free trade agreements we negotiated with Chile and Singapore as well as in the Free Trade Area of the Americas (FTAA) and other FTAs currently under negotiation and yet to be launched. Moreover, our proposals in these negotiations will further update copyright and enforcement obligations to reflect the technological challenges we face today as well as those that may exist at the time negotiations are concluded.

## **Government Use of Software**

In October 1998, the United States announced a new Executive Order directing U.S. Government agencies to maintain appropriate and effective procedures to ensure legitimate use of software. In addition, USTR was directed to undertake an initiative to work with other governments, particularly those in need of modernizing their software management systems or about which concerns have been expressed, regarding inappropriate government use of illegal software.

The United States has achieved considerable progress under this initiative. Countries that have issued decrees mandating the use of only authorized software by government ministries include Bolivia, China, Chile, Colombia, Costa Rica, the Czech Republic, France, Ireland, Israel, Jordan, Paraguay, Thailand, the U.K., Spain, Peru, Greece, Turkey, Hungary, Korea, Hong Kong, Macau, Lebanon, Taiwan and the Philippines. Ambassador Zoellick was pleased that these governments have recognized the importance of setting an example in this area and expects that these decrees will be fully implemented. The United States looks forward to the adoption of similar decrees, with effective and transparent procedures that ensure legitimate use of software, by additional governments in the coming year.

## **Intellectual Property and Health Policy**

In announcing the results of the 2003 Special 301 review, Ambassador Zoellick reiterated that USTR would not change the present approach to health-related intellectual property issues. That is to say, consistent with the United States' protection of intellectual property, we remain committed to working with countries to develop workable programs to prevent and treat HIV/AIDS, malaria, tuberculosis and other epidemics.

We have informed countries that, as they take steps to address a major health crisis like the HIV/AIDS crisis in sub-Saharan Africa, they should be able to avail themselves of the flexibilities afforded by the TRIPS Agreement, provided that any steps they take comply with

the provisions of the Agreement. The Declaration on the TRIPS Agreement and Public Health agreed upon at the WTO Doha Ministerial in November 2001 is a reflection of this commitment.

The U. S. Government also remains committed to a policy of promoting intellectual property protection, including for pharmaceutical patents, because of intellectual property rights' critical role in the rapid innovation, development, and commercialization of effective and safe drug therapies. Financial incentives are needed to develop new medications. No one benefits if research on such products is discouraged.

## **WTO Dispute Settlement**

The focus this year is on resolving the WTO disputes that were announced through previous Special 301 determinations, either through informal consultations and settlement, which can be more efficient and are therefore the preferred manner of resolving disputes, or where those are unsuccessful, through full utilization of the dispute settlement process . The following section provides updates of previously announced WTO cases, highlighting the progress made in the past year.

### **ARGENTINA**

On May 6, 1999, the United States filed a WTO dispute settlement case challenging aspects of Argentina's system of patent protection and protection for confidential test data. In late April 2002, the United States and Argentina agreed to harvest progress made during consultations and partially settle this dispute.

On the two outstanding issues that remain, that of data protection and the ability of patentees to amend pending applications to claim certain enhanced protection provided by the TRIPS Agreement, the United States retained its right to seek resolution under the WTO dispute settlement mechanism and is currently working with Argentina to resolve these issues.

### **EUROPEAN UNION**

At the conclusion of the 1999 Special 301 review, the United States initiated a WTO dispute settlement case against the EU, based on the apparent TRIPS deficiencies in EU Regulation 2081/92, which governs the protection of geographical indications (GIs) for agricultural products and foodstuffs in the EU. The regulation appears to deny national treatment to foreign GIs. According to the plain language of the regulation, only EU GIs may be registered. With respect to trademarks, the regulation permits dilution and even cancellation of trademarks when a GI is created later in time. Our initial WTO consultation request alleged that this regulation denies national treatment to foreign geographical indications, and does not provide sufficient protection to trademarks that are similar or identical to a GI and appears, therefore, in violation of the

Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). The United States requested consultations regarding this matter on June 1, 1999, and numerous consultations have been held since then. The United States appreciates that the EU has recently issued some amendments to its regulation. However, these amendments do not address our principal concerns with respect to full national treatment and appropriate protection for trademarks.

On April 4, 2003, the United States submitted an additional request for consultations on EU Regulation 2081/92 to the EU. This additional request alleges that the EU Regulation is not consistent with the national treatment obligations and the most-favored-nation obligations of Articles I and III of the General Agreement on Tariffs and Trade 1994. In this request, we have also reiterated the concerns raised in our original consultation request. Under WTO rules, other Members may request to join consultations if they share our concerns and have a substantial trade interest. In addition, Australia has requested separate consultations with the EU regarding Regulation 2081/92.

The United States will continue to seek a solution with the EU while remaining prepared to take any appropriate action to pursue its rights in this matter.

#### ***Potential Dispute Settlement Cases***

No new dispute settlement proceedings are being announced at this time. However, the United States will continue to monitor WTO Members' compliance with the TRIPS Agreement and remains prepared to take appropriate action when necessary.

Several countries do not appear to meet their TRIPS obligations. The United States will consider all options, including but not limited to possible initiation of new WTO dispute settlement cases, in working with these countries toward full TRIPS implementation. The United States will continue to consult in the coming months with all of these countries in an effort to encourage them to resolve outstanding TRIPS compliance concerns as soon as possible.