

2002 SPECIAL 301 REPORT

Executive Summary

United States Trade Representative Robert B. Zoellick today announced the results of the 2001 "Special 301" annual review, which examined in detail the adequacy and effectiveness of intellectual property protection in approximately 72 countries.

USTR notes with disappointment the continued designation of Ukraine as a Priority Foreign Country due to its 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, the \$75 million worth of sanctions imposed on Ukrainian products on January 23, 2002, 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 in such trading partners as Brazil, Colombia, India, Hungary, Taiwan, the Dominican Republic, Kuwait, the Philippines, Russia, Egypt, Turkey, Saudi Arabia, Uruguay, and members of the Andean Community. While not listing Mexico, enforcement efforts in Mexico continue to need improvement and an out-of-cycle review will be conducted later this year. 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). Such countries include Hungary, members of the Andean Community, the Dominican Republic, India and Kuwait.

In this year's review, USTR devoted special attention to the growing issue of Internet piracy, as well as the ongoing campaign to reduce production of unauthorized copies of "optical media" products such as CDs, VCDs, DVDs, and CD-ROMs. Optical disk piracy is an increasing problem in many countries, in particular, Ukraine, Indonesia, Malaysia, the Philippines, Russia, Thailand and Taiwan. In addition, USTR continued to focus on other critically important issues including 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 continued to encourage countries to ensure that government ministries use only authorized software.

Over the past year, progress was made by many developing countries and by newly acceding WTO Members 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. As part of the negotiations with Chile and Singapore, as well as in the hemispheric Free Trade Area of the Americas, we are seeking higher levels of intellectual property protection in a number of areas covered by the TRIPS Agreement. These negotiations, as well as any other negotiations that USTR may undertake in the course of this year, give us the opportunity to build upon the standards in the TRIPS Agreement to reflect the technological changes that have occurred since the late 1980s and early 1990s.

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, the Dominican Republic, and Turkey including through implementation of the Generalized System of Preferences and other trade preference programs.

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, as well as 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.

These Treaties represent the consensus view of the world community that the vital framework of protection under existing treaties, 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, which clarify exclusive rights in the on-line environment and specifically prohibit the devices and services intended to circumvent technological protection measures for copyrighted works.

We are pleased to report that as of May 20, 2002, both Treaties will be in effect, as the

required number of ratifications have been deposited in Geneva with WIPO. We continue to work internationally to promote ratification of these Treaties by other trading partners. These Treaties represent the current state of international copyright law and provide the critical foundation needed to enable e-commerce to flourish. These treaties provide necessary tools to combat piracy on the Internet.

The United States is also pleased to learn that Japan has recognized the need to protect temporary copies of works and phonograms. This is an important improvement in Japan's protection of copyright and related rights. Unfortunately, Japan's ability to develop a vibrant e-commerce market in works protected by copyright and related rights is now hampered by the enactment of an Internet service provider liability law which fails to provide the necessary protections to right holders. The U.S. encourages Japan best chance to improve this situation by adopting implementing regulations which, without imposing unfair or unequal burdens, provide the necessary incentives for service providers to work with right holders to remove infringing material expeditiously without discriminating against individual right holders, and to provide right holders the ability to learn the identity of accused online infringers.

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 have already 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 are negotiating with Chile and Singapore as well as the Free Trade Area of the Americas (FTAA), and other FTAs 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 several years from now.

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 – to implement 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 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 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.

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, and 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 challenge of pirate optical media production within their borders, or the threat of such production developing, to adopt similar controls, or aggressively enforce existing regulations, in the coming year. USTR is concerned, however, 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, including the enactment of optical media controls. Particularly troubling are reports that the CD plant licensing laws might be revised in such a manner so as to undermine, not improve, their effectiveness. We will be closely monitoring the situation and look to the Government of Bulgaria to maintain strong optical disk (OD) regulations.

Government Use of Software

In October 1998, the United States announced a new Executive Order directing U.S. Government

agencies to maintain appropriate, 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, the Czech Republic, Ireland, Israel, Jordan, Paraguay, Thailand, France, the U.K., Spain, Greece, Turkey, Hungary, Korea, Hong Kong, Macau, Lebanon, Taiwan and the Philippines. Ambassador Zoellick noted his pleasure that these governments have recognized the importance of setting an example in this area and his expectation 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 2002 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

In past years, USTR has used the annual Special 301 report as a vehicle to announce the launch of WTO dispute settlement proceedings against countries that have not met their TRIPS obligations. As with last year's report, the focus this year is on resolving the WTO cases that were announced through previous Special 301 determinations, either through full utilization of the dispute settlement process (*e.g.*, panel proceedings, Appellate Body review, and reasonable period of time arbitration), or through consultations, which are more efficient and are therefore the preferred manner of reaching mutually satisfactory solutions. The following section provides updates of previously announced WTO cases,

highlighting the progress made in the past year.

ARGENTINA

On May 6, 1999, as a result of the 1999 Special 301 determinations, the United States filed a WTO dispute settlement case challenging Argentina's failure to provide a system of exclusive marketing rights for pharmaceutical products, and to ensure that changes in its laws and regulations during its transition period do not result in a lesser degree of consistency with the TRIPS Agreement. Subsequently, as announced in the 2000 Special 301 Report, the United States expanded its claims to include new concerns that arose due to Argentina's failure to fully implement its remaining TRIPS obligations that came into effect on January 1, 2000. These concerns include Argentina's apparent failure to protect confidential test data submitted to government regulatory authorities for marketing approval for pharmaceuticals and agricultural chemicals; denial of certain exclusive rights for patents; failure to provide such provisional measures as preliminary injunctions to address patent infringement; and exclusion of certain subject matter from patentability. In all, the United States raised ten distinct claims with Argentina in this dispute. Consultations were then held on July 17, 2000, November 29, 2000, April 2, 2001, July 13, 2001, September 21, 2001, and November 5, 2001. Progress was made during these consultations, and on the week of April 15, 2002, in meetings held in Buenos Aires, the United States and Argentina agreed to harvest the progress made and finalized the elements of a joint notification to the WTO, partially settling this dispute.

In the joint notification to the WTO, Argentina clarified how certain aspects of its intellectual property system, such as those related to its exclusive marketing rights regime, operate so as to conform with the TRIPS Agreement. In addition, Argentina agreed to amend its patent law to provide protection for products obtained from a process patent, to ensure that preliminary injunctions are available in intellectual property court proceedings, and to shift the burden of proof from the plaintiff to the defendant in civil proceedings involving process patents. Finally, 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.

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 protected. Foreign GIs cannot be registered in the EU, and thus are not eligible for protection. In addition, although the Regulation permits EU nationals to oppose or cancel GIs, non-EU nationals are prohibited from raising any objections. With respect to trademarks, the Regulation permits dilution and even cancellation of trademarks when a GI is created later in time. The United States requested consultations regarding this matter on June 1, 1999, and numerous consultations have been held since then. In March of this year, the EU produced proposed

amendments to the Regulation. Although the proposal, as written, would address some of the deficiencies of the Regulation, it is lacking in several significant respects, including its treatment of foreign GIs. We are exploring the possibility of addressing these concerns in order to reach a satisfactory settlement with the EU. If a mutually agreeable solution can not be found, the United States may have no option but to continue to pursue resolution through WTO dispute settlement procedures.

BRAZIL

The 2000 Special 301 report announced our initiation of a WTO dispute against Brazil over a longstanding issue between the two countries regarding Article 68 (1) (I) of Brazil's patent law, which requires all patent owners to manufacture their patented products in Brazil or else be subject to the compulsory licensing of their patents. This appears to be in violation of TRIPS Article 27.1, which prohibits Members of the WTO from discriminating on the basis of "...whether the products are imported or locally produced." The United States continues to question whether such a requirement is consistent with Brazil's obligations under the TRIPS Agreement. In June 2001 the United States and Brazil reached an agreement to transfer our dispute to a newly formed U.S.-Brazil Bilateral Consultative Mechanism. Under the Consultative Mechanism, the United States will receive advance notice from the Government of Brazil should it decide to use Article 68 (1) (I). The United States has fully reserved all of its WTO rights in this matter. The establishment of the Consultative Mechanism is a step forward in resolving this dispute with Brazil.

Potential Dispute Settlement Cases

No new dispute settlement proceedings are being announced at this time. However, the United States is actively considering the initiation of new WTO cases for later this year or early next year against certain WTO Members that appear not to be in compliance with their TRIPS obligations.

One area that we continue to monitor closely is the protection of confidential test data. We note, in particular, that we have serious concerns with Hungary's failure to adequately protect confidential test data associated with applications for marketing approval submitted by pharmaceutical companies, in apparent violation of Article 39.3 of the TRIPS Agreement. Specifically, Hungary does not provide protection against the unfair commercial use of test or other data submitted to its regulatory authorities in order to obtain marketing approval. As a result, generic pharmaceutical companies have been permitted to rely on data generated and submitted at great cost and effort by innovator companies -- without their consent -- almost immediately after the original applications for marketing approval have been filed. U.S. industry estimates that it loses between \$50 million and \$100 million annually due to the TRIPS Article 39.3 problem and other weaknesses in Hungary's data protection regime.

Other countries that do not appear to meet their TRIPS obligations include several countries in the Andean Community, as well as the Dominican Republic, India, Israel and Kuwait. 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.