2004 SPECIAL 301 REPORT

Executive Summary

United States Trade Representative Robert B. Zoellick today announced the results of the 2004 "Special 301" annual review, which examined in detail the adequacy and effectiveness of intellectual property protection in approximately 85 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 in sanctions imposed on Ukrainian products on January 23, 2002 will remain in place. This continued failure to protect intellectual property rights (IPR) 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 encourage Ukraine to combat piracy and to enact the necessary IPR laws and regulations.

Addressing weak IPR protection and enforcement in China is one of the Administration's top priorities. At the April 2004 meeting of the Joint Commission on Commerce and Trade (JCCT), the United States secured a commitment from China's Vice Premier Wu Yi that China will undertake a series of actions to significantly reduce IPR infringements throughout the country. These actions, outlined in the China section of the report, are critical in light of the rampant counterfeit and piracy problems that plague China's domestic market and the fact that China has become a leading exporter of counterfeit and pirated goods to the world. We will be monitoring implementation of these commitments closely through a Joint IPR Working Group formed through the JCCT and will assess China's progress on their commitments through an out-of-cycle review in early 2005.

The Special 301 report addresses significant concerns with respect to such trading partners as Argentina, The Bahamas, Brazil, Egypt, India, Indonesia, Israel, Korea, Kuwait, Lebanon, Pakistan, Paraguay, The Philippines, Poland, Russia, Taiwan, Thailand, and Turkey. In addition, the report notes that the United States will consider all options, including but not limited to initiation of dispute settlement consultations, in cases where countries 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 increasingly important issue of the need for significantly improved enforcement against 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 Brazil, Bulgaria, India, Indonesia, Lebanon, Mexico, Pakistan, Paraguay, The Philippines, Russia, Venezuela, and Vietnam. The issue in these and other countries ultimately is one of the foreign government's political will to effectively address piracy and counterfeiting. The annual Special 301 process and report send a message to the governments of countries where serious IP-related problems exist. In addition, USTR continues to focus on other critically important issues, including internet piracy, proper implementation of the TRIPS Agreement by developed and 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, the levels of 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 (FTAs). We are pleased that the recently concluded FTAs with Central America including the Dominican Republic, Morocco and Australia will strengthen the protection of IPR in those countries. Specifically, the intellectual property chapters of these 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 Bahrain, Panama, the Southern Africa Customs Union, in the upcoming FTA negotiations with Andean countries and Thailand, and in the ongoing negotiation of a Free Trade Area of the Americas. Another opportunity we are using to strengthen the protection and enforcement of intellectual property is the increasing number of trade and investment framework agreement (TIFA) negotiations with several countries in regions such as the Middle East and Asia.

USTR will also continue to use all statutory tools, as appropriate, to improve intellectual property protection in countries where it is inadequate, including through implementation of the Generalized System of Preferences, other trade preference programs, and ongoing GSP reviews of countries including Brazil, the Dominican Republic, Kazakhstan, Lebanon, Russia, and Uzbekistan.

Global Scourge of Counterfeiting and Piracy

Counterfeiting and digital piracy have increased dramatically in recent years and are areas of particular concern in this year's report. 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, print (e.g., books, journals and other printed materials) and other analogue formats, as well as counterfeiting of all types of trademarked products, have grown to such a scale because these illegal activities offer 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 actually imposed in many countries are so low that they offer no deterrent.

The most significant piracy and counterfeiting problems require measures that may go beyond the

minimum standards of TRIPS to ensure effective enforcement at the national and local levels, including free trade zones in countries such as Belize, Panama and the United Arab Emirates. The global scourge of piracy and counterfeiting requires stronger and more effective border enforcement to stop the import, export, and transit of pirated and counterfeit goods.

This is why USTR seeks through our FTAs and our bilateral consultations to ensure that criminal penalties are high enough to have a deterrent effect, both in the law and as imposed by the courts and administrative bodies, 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 pirate activity, over the past year some of our trading partners, such as the Philippines and Poland, 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 India, Indonesia, Lithuania, Pakistan, Russia, Thailand and Ukraine have not made sufficient progress in this regard.

Governments, such as those of Hong Kong and Macau that implemented optical media controls in previous years have clearly demonstrated their commitment to continue to enforce these measures. Taiwan and Malaysia are steadily improving their enforcement as well. 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.

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 IPR enforcement. 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 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 IPR priorities. 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.

Developing countries continue to make progress 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. Agency for International Development, the U.S. Customs and Border Protection, the Justice Department, and the Commerce Department's Commercial Law Development Program on a country-by-country basis, as well as in group seminars, including those co-sponsored with the World Intellectual Property Organization (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 of the key implementation priorities that we have focused on in this year's review is the implementation of Article 39.3 of the TRIPS Agreement, which requires WTO Members to protect test data submitted by drug companies to health authorities[1] 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 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, China, the Czech Republic, Estonia, Japan, Jordan, Korea, Mexico, New Zealand, Slovenia, and Switzerland. We commend Bulgaria and Colombia on their recent implementation of data protection for pharmaceutical and agricultural chemical products, respectively. In addition, we commend Mexico for passage of regulations that strengthen the coordination between its health and patent agencies to protect valid patents of innovative pharmaceutical products. We urge all WTO members to swiftly complete their implementation of Article 39.3, including the rest of the Andean countries, Israel and Turkey.

As more countries fulfill their implementation obligations, we will adjust our focus to determine whether our trading partners are providing adequate and effective enforcement as required by the TRIPS enforcement provisions.

[1] 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.

Internet Piracy and the WIPO Copyright Treaties

The Internet has undergone explosive growth and, coupled with increased availability of broadband connections, serves as an extremely efficient global distribution network for pirate products. The explosive growth of copyright piracy on the Internet is a serious problem. We are continuing to work with other governments, and consult 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 WIPO when it concluded two copyright treaties in 1996: the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty, 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 have been successful in this effort by incorporating the standards of the WIPO Internet Treaties as substantive obligations in all our FTAs to date, and continue to pursue this goal in 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 an 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 government use of illegal software.

The United States has achieved considerable progress under this initiative. Countries and territories that have issued decrees mandating the use of only authorized software by government ministries include Bolivia, Chile, China, Colombia, Costa Rica, the Czech Republic, France, Greece, Hong Kong, Hungary, Ireland, Israel, Jordan, Korea, Lebanon, Macau, Paraguay, Peru, the Philippines, Spain, Taiwan, Thailand,

Turkey, and the United Kingdom. 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

At the WTO Doha Ministerial in November 2001, WTO Ministers issued a separate Declaration on the TRIPS Agreement and Public Health. In paragraph 6 of the Declaration, Ministers recognized that WTO Members with "insufficient or no manufacturing capacities in the pharmaceutical sector" could have difficulty using the compulsory licensing provisions of the TRIPS Agreement.

On August 30, 2003, the WTO General Council adopted the TRIPS/health "solution," which is comprised of a Decision and an accompanying Chairman's Statement that sets out the shared understandings of WTO Members on how the Decision should be interpreted and applied. Under the solution, Members waive Article 31(f) to allow Members to issue compulsory licenses to export pharmaceutical products under certain circumstances.

Under the terms of the solution, a country may issue a compulsory license to export needed pharmaceuticals to a country that lacks manufacturing capacity. The solution requires exporting and importing countries to comply with certain transparency and notification obligations. It also requires countries and companies to adopt specified anti-diversion measures (e.g., differential coloring/shaping/packaging of pills) to ensure that drugs reach the intended recipients and are not diverted to more lucrative markets. The Chairman's Statement emphasized the importance of the purpose of the solution and noted that the solution was not to be used as an instrument to pursue industrial or commercial policy objectives.

The TRIPS Council was instructed to incorporate the waiver into an amendment of the TRIPS Agreement by June 2004. We support an amendment that reflects the agreement reached in August 2003, and will work towards that goal. In the meantime, the solution will continue to be available.

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.

Regulation and Sustainable Innovation

The ability of innovative industries to continue to develop new products depends largely upon two factors: (1) a strong and effective intellectual property system; and (2) a regulatory regime that allows industry to market new products during the period of time when the exclusive intellectual property rights exist. While intellectual property is a necessary condition for encouraging innovation, it is the ability to market products effectively that provides the incentive for continued innovation and generates the returns on investment necessary to fund new investment. This cycle of innovation produces significant social benefits by accelerating economic growth and raising standards of living.

The Special 301 process focuses on intellectual property protection, and this has been the primary subject

of industry comments. In addition, however, industries – and in particular the pharmaceutical industry – have focused attention on regulatory regimes that impede their ability to sustain the cycle of innovation. These types of regulatory barriers include, for example, non-transparent administrative regimes; decision-making that lacks a scientific basis; and cumbersome and lengthy drug listing and other administrative processes.

In the conference report accompanying the Medicare Prescription Drug, Improvement and Modernization Act of 2003, the Congress directs the Secretary of Commerce, in consultation with the International Trade Commission, the Secretary of Health and Human Services and the United States Trade Representative, to prepare a report designed in part to provide an "[e]stimate of the impact . . . price controls, intellectual property laws and other such measures have on fair pricing, innovation, generic competition, and research and development in the United States and each" OECD country identified Regarding price controls, the conference report directs the Administration to examine drug pricing practices of OECD countries and assess, among other things, whether "those practices utilize nontariff barriers with respect to trade in pharmaceuticals."

The conference report reflects a concern that the regulatory practices of many countries may be slowing the development of the next generation of life saving drugs. Implicit in this proposition is a concern that, by adopting such mechanisms, foreign countries have chosen to rely excessively on U.S. research and development for new life saving medicines.

The United States has, in the past, worked with countries such as Australia, Japan, and Korea to address these types of issues. The Administration is engaged in the process of preparing the report Congress mandated, and will examine other country practices including, for example, those of Canada and Germany.

Canada's Patented Medicine Prices Review Board (PMPRB) regulates patented pharmaceutical products but not generic products. The PMPRB establishes the guidelines that companies use to set prices for drugs and then limits further increases. Under the PMPRB's pricing system, the price for a new innovative drug cannot exceed the median of prices in seven developed countries that Canada uses as a basis for comparison (the United States, the United Kingdom, France, Germany, Sweden, Switzerland, and Italy).

Germany is in the process of developing a reference pricing system. For 2004, the government mandated a 16% rebate on pharmaceuticals - this is scheduled to be replaced by a reference pricing scheme, the details of which are being debated now. It currently appears that, under the reference pricing system, the government is considering setting pharmaceutical prices by category of pharmaceutical, which might also include both patented and generic drugs.

It is important to understand how these types of regulatory regimes affect patient welfare, research and development funding, and innovation. This analysis, coupled with the ongoing analysis of global IP protection through the Special 301 process, should provide a more complete picture of the impact of regulatory and IP regimes on innovation.

WTO Dispute Settlement

Dispute settlement efforts this year continue to focus on resolving disputes that were announced through previous Special 301 determinations, using the full range of tools available. These tools include informal consultations and settlement, which can be more efficient and are therefore the preferred manner of

resolving disputes, or where those are unsuccessful, full utilization of the dispute settlement process. The United States resorted to dispute settlement in August of 2003 by requesting the establishment of a Panel to examine the European Communities' discriminatory regime for protection of geographical indications for agricultural products and foodstuffs. The following section provides updates of this and previously announced WTO cases.

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 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 while continuing to work toward a resolution with Argentina.

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.

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, the United States also reiterated the concerns raised in its 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.

In August 2003, the United States requested the establishment of a WTO dispute settlement panel to review the consistency of the EU Regulation 2081/92 with WTO rules. That proceeding is now ongoing.

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.

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.