

## **2005 SPECIAL 301 REPORT**

### **EXECUTIVE SUMMARY**

The 2005 “Special 301” annual review examines in detail the adequacy and effectiveness of intellectual property rights (IPR) protection in 90 countries. Based on a lengthy process of information-gathering and analysis, the United States Trade Representative (USTR) has identified 52 countries that are designated in the categories of Priority Foreign Country, Section 306 Monitoring, Priority Watch List, or Watch List. The Special 301 Report reflects the Administration’s resolve to take consistently strong actions under the Special 301 provisions of the Trade Act.

This Administration is determined to ensure the adequate and effective protection of intellectual property and fair and equitable market access for U.S. products. The designations and corresponding requisite measures announced today result from close consultations with affected industry groups, other private sector representatives, and Congressional leaders, and demonstrate the Administration's commitment to use all available methods to resolve IPR issues.

Addressing weak IPR protection and enforcement in China continues to be one of the Administration’s top priorities. These IPR issues, outlined in the China section of the Special 301 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. In the China section of the Special 301 Report, we are announcing the results of the out-of-cycle review conducted in early 2005. This year’s Special 301 Report also sets forth the United States’ plan to work with U.S. industry and other stakeholders to further build a factual record and to develop arguments with an eye toward utilizing World Trade Organization (WTO) procedures to bring China into compliance with its WTO Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) obligations, to invoke the transparency provisions of the TRIPS Agreement, to elevate China to the Priority Watch List, and to maintain Section 306 monitoring. We will be monitoring closely China’s IPR activities throughout the coming year.

USTR notes the continued need for Ukraine 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, first imposed on Ukrainian products on January 23, 2002, will remain in place. Ukraine’s failure to protect IPR jeopardizes its efforts to join the WTO and undermines its ability to attract trade and investment. The United States notes with optimism, however, that Ukraine has recently renewed efforts to enact needed optical media legislative amendments, and has expressed its commitment to resolving IPR issues. The United States encourages Ukraine to enact necessary IPR laws and regulations as well as increase its enforcement efforts to combat piracy, and today announces the commencement of a Special 301 out-of-cycle review to monitor Ukraine’s progress in providing effective copyright protection and IPR enforcement.

The Special 301 report addresses significant concerns with respect to such trading partners as Argentina, Brazil, Egypt, India, Indonesia, Israel, Kuwait, Lebanon, Pakistan, Paraguay, the Philippines, Russia, Turkey, and Venezuela. 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 TRIPS Agreement.

In this year's review, USTR devotes special attention to the need for significantly improved enforcement against counterfeiting and piracy. We place particular emphasis on the ongoing campaign to reduce production of unauthorized copies of optical media products such as compact discs (CDs), video compact discs (VCDs), digital versatile discs (DVDs), and compact disc read-only memory (CD-ROMs), as well as on the counterfeiting of trademarked goods. Optical media piracy and trademark counterfeiting are increasing problems in many countries, including Brazil, Bulgaria, China, India, Indonesia, Lebanon, Mexico, Pakistan, Paraguay, the Philippines, Russia, Thailand, Venezuela, and Vietnam. At issue in these and other countries is the foreign governments' political will to effectively address piracy and counterfeiting. 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 insist that other countries' government ministries use only authorized software.

Over the past year, many developing countries and newly acceding WTO Members have made progress toward implementing their TRIPS obligations. Nevertheless, full implementation of TRIPS Agreement obligations has yet to be achieved in certain countries, particularly with respect to the TRIPS Agreement's enforcement provisions. Levels of piracy and counterfeiting of intellectual property remain unacceptably high in these countries. The annual Special 301 review provides an opportunity to assess these issues, and the Special 301 Report sends a necessary message to the governments of countries where serious IPR-related problems exist.

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). The intellectual property chapters of the FTAs provide for higher levels of intellectual property protection in a number of areas covered by the TRIPS Agreement. We are pleased that the recent FTAs with Morocco and Australia will strengthen the protection of IPR in those countries. When the pending Bahrain FTA and Central American Free Trade Agreement (CAFTA-DR) (with Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and the Dominican Republic) are adopted, we look forward to seeing strengthened IPR regimes in those countries as well. We are also seeking higher levels of protection and enforcement in the FTAs that are currently under negotiation with Panama, Thailand, the Southern Africa Customs Union, the Andean countries, the United Arab Emirates, and Oman, 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 continue to use all statutory tools, as appropriate, to improve intellectual property protection in countries where it is inadequate. For example, USTR examines IPR practices through the implementation of trade preference programs, such as the ongoing Generalized System of Preferences (GSP) reviews of countries, including Brazil, Kazakhstan, Lebanon, Pakistan, Russia, and Uzbekistan.

### **Global Scope of Counterfeiting and Piracy**

Global IPR theft and trade in fakes have grown to unprecedented levels, threatening innovative and creative economies around the world. Counterfeiting and digital piracy remain areas of particular concern in this year's report. Counterfeiting has developed from a localized industry concentrated on the copying of high-end designer goods into a massive, sophisticated global business involving the manufacturing and sale of counterfeit versions of a vast array of products, including soaps, shampoos, razors, batteries, cigarettes, alcoholic beverages, golf clubs, automobile parts, motorcycles, medicines, and health care products, to name a few. 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 generally pay neither taxes nor duties, and do not comply with basic manufacturing standards for the health and safety of workers or product quality and performance. Piracy of copyrighted products in digital, print (e.g., books, journals, and other printed materials), and other analog formats, as well as counterfeiting of all types of trademarked products, have grown rapidly because these illegal activities offer enormous profits and little risk for the criminal element of society. Criminals can enter into the counterfeiting and pirating 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 global scope of piracy and counterfeiting requires stronger and more effective border enforcement to stop the import, export, and transit of pirated and counterfeit goods. For example, effective enforcement efforts are needed at the national and local levels in free trade zones in Belize, Panama, and the United Arab Emirates.

This is why USTR seeks through our FTAs and our bilateral consultations to maximize the deterrent effect of remedies, including requirements that pirated and counterfeit products, as well as the equipment used to make them, are seized and destroyed. 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-\$250 billion per year.

### **STOP! Initiative**

USTR is actively engaged in implementing the Administration's Strategy Targeting Organized Piracy (STOP!) initiative. Announced in October 2004, STOP! brings together all the major players – the federal government, private sector and trade partners – to take concerted action in

cracking down on piracy and counterfeiting. The initiative is part of an effort to enhance coordination among all relevant U.S. Government agencies and U.S. trading partners to tackle this global problem. As part of STOP!, USTR is advocating international adoption of best practices guidelines incorporating enhanced enforcement disciplines drawn from the IP chapters of recent FTAs. USTR is also introducing in multilateral fora new initiatives to improve the global intellectual property environment that will aid in disrupting the operations of pirates and counterfeiters. Key initiatives are currently underway in the G-8, Organization for Economic Cooperation and Development (OECD), and the Asia-Pacific Economic Cooperation (APEC) forum. As part of the STOP! Initiative, USTR requests recommendations from interested parties on criteria to be used in the Special 301 Report with respect to individual businesses that have been found to have significantly infringed IPR.

### **Transshipment and Transiting of Goods**

“Transshipment” and “in transit goods” are expanding problems that USTR highlights in this year’s Special 301 Report. Transshipped goods enter the customs territory of a country, are transferred from one importing means to another, and then leave from the same port for another destination. In transit goods, on the other hand, move “under customs control” from one customs office to another customs office. In transit goods may move entirely within one customs territory or may cross borders from one customs territory to another customs territory. Frequently goods moving under one of these procedures will be “diverted” for consumption into the customs territory where they first arrive. Transshipped and in transit goods pose a high risk for counterfeiting and piracy because those customs procedures may be used to disguise the true country of origin of the goods or to enter goods into customs territories where border enforcement for transshipped or in transit goods is known to be weak with the intention of passing the goods through those customs territories to their destination. The Special 301 Report notes that transshipment or in transit goods are growing problems in Ukraine, Belize, Canada, Latvia, Lithuania, Taiwan, and Thailand. We urge these countries to provide stronger intellectual property border enforcement protections, and the United States will work together with these countries to improve their IPR border enforcement systems.

### **Free Trade Zones**

We are concerned with the growing problem of pirated and counterfeit goods moving through “free trade zones,” which are geographic areas considered to be outside of a nation’s customs territory for the purposes of collecting import duties and taxes. Free trade zones range in size from small commercial warehouses to complexes housing hundreds of businesses. Free trade zones are generally established by governments to promote legitimate trade and offer the advantage of providing a free trading environment whereby a minimum level of regulation is demanded of companies approved to operate within them. Permissible operations within free trade zones include preserving goods, preparing goods for shipping, and handling goods in order to improve their packaging or marketing to manufacturing processes. Free trade zones present a considerable risk, however, of serving as a conduit for counterfeit and pirated goods, and as a situs of manufacturing of IPR infringing goods. The United States has received complaints from U.S. industry regarding the Colon Free Zone in Panama, the Jebel Ali Free Zone in the United Arab Emirates, the Corozal Commercial Free Trade Zone in Belize, and the Manaus Free Trade

Zone in Brazil, among others. The United States urges all countries having free trade zones located within their territories to bring the operation of the free trade zones under the rule of law and its consistent application. The United States is working with Panama through the FTA negotiations to strengthen IPR enforcement in Panama's Free Zones.

### **Controlling Optical Media Production**

Over the past year some of our trading partners, such as the Philippines, Poland, and Indonesia, have taken important steps toward implementing much-needed controls on optical media production in order to address and prevent future pirate activity. We have seen particular progress this year in the Philippines' enforcement of its optical media law. However, other countries urgently need to implement controls or improve existing inadequate measures, including India, Pakistan, Russia, Ukraine, Thailand, and Bulgaria, none of which have made sufficient progress in this regard. Some governments, such as those of Hong Kong and Macau, which implemented optical media controls in previous years, have clearly demonstrated their commitment to continue to enforce these measures. Malaysia is steadily improving its enforcement efforts, and Taiwan continues to make significant progress in providing improved IPR enforcement. 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 subject to mandatory dispute settlement provisions.

Developed countries were required to fully implement the TRIPS Agreement as of January 1, 1996, while developing countries were given a transition period for many obligations until January 1, 2000. Ensuring that developing countries are in full compliance with the TRIPS Agreement obligations now that this transition period has come to an end is one of this Administration's highest IPR priorities. The least-developed countries have until January 1, 2006 to implement the TRIPS Agreement, and the United States looks forward to the successful completion of this transition. However, in order to address the concerns raised by the least-developed countries, the United States suggested, and all other WTO members agreed, to extend the transition period for ten years, until 2016, for the least-developed countries to implement their TRIPS obligations for patent and data protection for pharmaceutical products.

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 IPR enforcement mechanisms. Every year the U.S. Government provides extensive technical assistance and training on the implementation of the

TRIPS Agreement 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 Department of State, the U.S. Agency for International Development, U.S. Customs and Border Protection, the Department of Justice, and the Department of Commerce. This assistance is provided 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. In addition, U.S. industry is actively involved in providing specific enforcement-oriented training in key markets around the world. Technical assistance involves the review of, and drafting assistance on, laws concerning intellectual property and enforcement. Training programs usually cover the substantive provisions of the TRIPS Agreement, including IPR 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 in which additional progress is not achieved, the United States will consider other means of encouraging implementation, including the possibility of dispute settlement consultations.

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 companies to health authorities against "unfair commercial use" for pharmaceutical and agricultural chemical products.<sup>1</sup>

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 a product identical to one that has already been approved. Generally, these second applicants may be required to demonstrate the bioequivalence of their products with the product of the first company, and will be allowed to rely on the test data, rather than 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 considerable effort involved in producing the safety and efficacy data needed to obtain marketing approval, the TRIPS Agreement requires that the original applicant must receive protection for that data against unfair commercial use. Accordingly, the United States and other countries provide a period of protection during which second-comers may not rely on the data submitted by the innovative company to obtain approval for their copies of the product. This means that, during the period of exclusivity, the data provided by the originator cannot be relied upon by regulatory officials to approve similar products. This period of protection is five years in the United States and six to ten years in the EU Member States. Other countries that provide a period of protection against reliance on data include Australia, China, Japan, Jordan, Korea, Mexico, New Zealand, and Switzerland. We commend Bulgaria on its recent implementation of data protection for pharmaceutical and agricultural chemical products. We urge all WTO members to swiftly complete their implementation of TRIPS Article 39.3, including certain Andean countries, Israel and Turkey.

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

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

The Internet has undergone explosive growth and, coupled with the increased availability of broadband connections, serves as an extremely efficient global distribution network for pirated 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 (WCT) and the WIPO Performances and Phonograms Treaty (WPPT) (collectively, the “WIPO Internet Treaties”). The WIPO Internet Treaties help to 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. As of April 29, 2005, there are 51 members of the WCT and 49 members of the WPPT; this number will rise significantly when the EU joins, which, by internal arrangement, is expected to occur when the last five EU Member States complete their implementation processes. Even more countries have implemented in their national laws key provisions of these treaties even though they have not yet formally ratified them. At this point, therefore, the WIPO Internet Treaties are now part of the international IPR legal regime and 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 heighten the standards of protection for intellectual property, by incorporating standards of the WIPO Internet Treaties as substantive obligations in the bilateral and regional trade agreements that we negotiate. Moreover, our proposals in our FTA negotiations will continue to include up-to-date 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. The United States is 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**

The Administration is dedicated to addressing the serious health problems, such as HIV/AIDS, afflicting African and other least-developed countries. The United States is firmly of the conviction that intellectual property protection, including for pharmaceutical patents, is critical to the long term viability of a health care system capable of developing new and innovative lifesaving medicines. Intellectual property rights are necessary to encourage 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.

At the same time, the United States is committed to the principle that international obligations such as the TRIPS Agreement have sufficient flexibility to allow countries, particularly developing and least-developed countries, to address the serious public health problems that they face.

At the WTO Doha Ministerial in November 2001, WTO Ministers issued a separate Declaration on the TRIPS Agreement and Public Health, acknowledging the serious public health problems afflicting Africa and other developing and least-developed countries, especially those resulting from HIV/AIDS, malaria, tuberculosis, and other epidemics. Ministers agreed that intellectual property rules contain flexibilities to meet the dual objectives of, on the one hand, meeting the needs of poor countries without the resources to pay for cutting edge pharmaceuticals and, on the other hand, ensuring that the patent rights system continues to promote the development and creation of new lifesaving drugs.

The United States proposed, and all WTO members agreed, that the Doha Declaration should provide an additional ten year transition period (until 2016) for least-developed countries to implement the pharmaceutical-related provisions of the TRIPS Agreement. This extended transition period balances the interests of intellectual property rights holders and the needs of the least-developed countries.

In addition, 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 and directed the TRIPS Council to find an expeditious solution to this problem. In December 2002, the United States



announced a framework to ease WTO rules to allow countries in need to import life-saving drugs.

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 are permitted, in accordance with specified procedures, to issue compulsory licenses to export pharmaceutical products to countries that cannot produce drugs for themselves.

The United States strongly supports effective and appropriate use of the TRIPS/health solution to facilitate access to life-saving medicines by countries in need. The United States would be willing to discuss the need to provide technical assistance if some Members encounter difficulties in implementing or utilizing the solution.

In fact, the United States has already taken steps to ensure that the solution can be implemented. For example, in July 2004, the United States reached an agreement with Canada to ensure that NAFTA's provisions will not impede implementation of the TRIPS/health solution.

The TRIPS Council is under instructions to incorporate the solution into an amendment of the TRIPS Agreement. The United States supports an amendment that reflects the agreement reached in August 2003, and will remain committed to working with the other Members to reach a consensus for an amendment as expeditiously as possible. In order to move towards an amendment, the United States submitted a paper at the March 2005 meeting of the WTO TRIPS Council expressing support for the amendment and setting out a simple and effective approach to do so. The solution will continue to be available as a WTO waiver until an amendment is finalized.

In the recent Free Trade Agreements with CAFTA-DR, Morocco, and Bahrain, the United States has clarified that the intellectual property provisions in the agreements do not stand in the way of measures necessary to protect public health. Specifically, the United States has confirmed that the intellectual property chapters of the FTAs do not affect the ability of the United States or our FTA partners to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency. The United States has also made clear that the intellectual property chapter of the FTAs will not prevent effective utilization of the TRIPS/health solution.

## **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) the capacity to market new products effectively during the period of time when the exclusive intellectual property rights exist. Although intellectual property protection is a necessary condition for encouraging innovation in all sectors, 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 research

and development and production of new products. This cycle of innovation produces significant economic and social benefits by accelerating economic growth and raising standards of living.

The Special 301 process focuses on analyzing the intellectual property protection and enforcement of our trading partners, 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 barriers that impede their ability to sustain the cycle of innovation and may inhibit the availability of new, ground-breaking products. 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 U.S. Medicare Prescription Drug, Improvement and Modernization Act of 2003 (House Report 108-391), the Congress directed 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 regarding trade in pharmaceuticals 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 pharmaceutical price controls, the conference report directed 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 directive reflects a concern in the United States that the regulatory practices of many other countries may be slowing the development of the next generation of life-saving drugs for use worldwide. Implicit in this proposition is a concern that, by adopting such mechanisms, foreign countries are not contributing adequately to research and development for new life-saving medicines.

The U.S. Department of Commerce released its report in December 2004, and found that regulatory practices in the OECD countries studied are reducing the funds available globally for pharmaceutical research and development and the creation of new, innovative life-saving drugs, and are driving up prices for generic pharmaceuticals. These practices include price controls, approval delays and procedural barriers, non-transparent processes, restrictions on dispensing and prescribing, and low reimbursement levels. The study also determined that addressing such practices in OECD countries would result in increased research and development in the pharmaceutical sector, development of three to four new innovative drugs each year, and lower prices of generic drugs.

The United States has worked with countries such as Australia, Japan, Korea, and China to address these types of issues and will continue to do so. Regarding Australia, our FTA has allowed us to address key issues relating to transparency and accountability that will improve market access for U.S. pharmaceutical companies. The Australian Government is following through on its commitments in this agreement, by setting up a transparent review system for appealing pharmaceutical listing decisions and working with U.S. officials to prepare for the first meeting of the Medicines Working Group.

With respect to Japan, pharmaceutical and medical device issues are an integral part of the Administration's regulatory reform work. The United States has made steady progress in improving transparency in this sector, ensuring that foreign pharmaceutical and medical device manufacturers have meaningful opportunities to provide input into important regulatory matters, and facilitating the introduction of innovative new pharmaceuticals and medical devices into the Japanese market.

Separately, the Administration has had a longstanding dialogue with Korea on pharmaceutical issues and, as a result, has seen considerable improvement over the past decade in U.S. pharmaceutical companies' access to the Korean market. The Administration is continuing these consultations and has made recent progress, focusing on further improvements in market access and transparency, and ensuring competition in this sector of the Korean market. In January, Korea's Health Insurance Reimbursement Agency began providing written justifications for its decisions on pricing and listing of new drugs.

With respect to China, the Administration has pressed the Government of China to price innovative drugs fairly and to add new drugs to its national formulary, which controls access to medicines for China's nearly 1.3 billion people. The Administration also is pressing the Government of China to address the production and export of counterfeit pharmaceuticals that both endanger lives and disrupt markets.

The Administration is examining other countries' 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 sets the launch price for drugs when they enter the market 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). In addition, Canada's pharmaceutical approval process is protracted and the procedures for provincial listing decisions can be lengthy and inconsistent.

Germany is in the process of implementing significant changes to its reference pricing system, which could impact the development and availability of innovative pharmaceuticals in that country. In 2004, the German Government required innovative drug makers to pay a 16 percent rebate on patent-protected pharmaceuticals (i.e., a mandatory price cut on patented-drug producers, but not generics). On January 1, 2005, Germany reduced the rebate to 6 percent, but put in place a reference pricing regime for patent-protected medicines. This new regime combines for the first time patent-protected and off-patent pharmaceuticals in "jumbo" reference pricing groups. This approach arbitrarily diminishes the value of innovative medicines by equating them with generic medicines for purposes of government reimbursement. Of the 12 new reference pricing groups established, four are jumbo groups, covering a wide range of innovative patented medicines. It has been estimated that reference price cuts for some of the most innovative drugs in the new jumbo groups are as much as 40 percent, which has the potential to affect the availability of such novel medicines and may lead to an increased burden on American patients in paying for the newest ground-breaking drugs. Although manufacturers

of patented pharmaceuticals can seek to have certain patented drugs excluded from the jumbo groups if they demonstrate that such products provide “significant therapeutic improvement,” only two patented drugs, produced by German and Swiss manufacturers, have been excluded and the process for determining whether a drug provides significant therapeutic improvement lacks transparency. The only two requests by U.S. manufacturers to exclude patented products from the new jumbo groups were rejected. The German Government may put additional classes of drugs under its jumbo reference pricing system later this year.

It is important to understand how these types of regulatory regimes affect patient welfare, research and development funding, and innovation. The Department of Health and Human Services, along with USTR and other U.S. health and economic policy agencies, are jointly approaching individual OECD countries through bilateral consultations, such as with Germany and Canada. USTR, in close coordination with U.S. health and other economic policy agencies, also will lead efforts with such countries in FTA negotiations, such as with Australia. These discussions are tailored to the specific circumstances of each country, but utilize a common set of principles aimed at advancing U.S. interests, including promoting innovation in the pharmaceutical sector and enhanced patient access to innovative and generic drugs. These efforts, coupled with the ongoing analysis of global intellectual property protection through the Special 301 process, should provide a more complete picture of the impact of regulatory and intellectual property protection regimes on innovation and offer potential opportunities to encourage continued strong development worldwide by innovative industries, such as the pharmaceutical sector.

### **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.

At the conclusion of the 1999 Special 301 review, the United States initiated dispute settlement consultations concerning the European Union’s (EU) regulation on food-related geographical indications (GIs), based on concerns that the regulation was inconsistent with the EU’s TRIPS Agreement obligations. These consultations were based on the United States’ long-standing complaint that the EU GI system discriminates against foreign products and persons – notably by requiring that EU trading partners adopt an “EU-style” system of GI protection – and provides insufficient protections to trademark owners. Because those consultations failed to resolve the matter, on August 18, 2003, the United States requested the establishment of a panel, and panelists were appointed on February 23, 2004.

On April 20, 2005, the WTO Dispute Settlement Body (“DSB”) adopted a panel report ruling in favor of the United States that the EU GI regulation is inconsistent with the EU’s obligations under the TRIPS Agreement and the General Agreement on Tariffs and Trade 1994. In the panel report adopted by the DSB, the panel agreed that the EU’s GI regulation impermissibly discriminates against non-EU products and persons. The panel also agreed with the United

States that Europe could not, consistent with WTO rules, deny U.S. trademark owners their rights; it found that, under the regulation, any exceptions to trademark rights for the use of registered GIs were narrow, and limited to the actual GI name as registered. The DSB recommended that the EU amend its GI regulation to come into compliance with its WTO obligations.

## **BACKGROUND ON SPECIAL 301**

The “Special 301” provisions of the Trade Act of 1974, as amended, require USTR to identify foreign countries that deny adequate and effective protection of intellectual property rights or fair and equitable market access for U.S. persons that rely on intellectual property protection. Special 301 was amended in the 1994 Uruguay Round Agreements Act to clarify that a country can be found to deny adequate and effective intellectual property protection even if it is in compliance with its obligations under the TRIPS Agreement. It was also amended to direct USTR to take into account a country's prior status under “Special 301,” the history of U.S. efforts to achieve stronger intellectual property protection, and the country’s response to such efforts.

Once the foreign countries are identified, the USTR is required to decide which, if any, should be designated a Priority Foreign Country, which is one that:

- (1) has the most onerous and egregious acts, policies, and practices which have the greatest adverse impact (actual or potential) on the relevant U.S. products; and
- (2) is not engaged in good faith negotiations or making significant progress in negotiations to address these problems.

If a trading partner is identified as a Priority Foreign Country, USTR must decide within 30 days whether to initiate an investigation of those acts, policies, and practices that were the basis for identifying the country as a Priority Foreign Country. A Special 301 investigation is similar to an investigation initiated in response to an industry Section 301 petition, in some circumstances.

In addition to identifying Priority Foreign Countries as required by statute, USTR also uses the Special 301 Report to identify "Priority Watch List" and "Watch List" countries or economies. Trading partners who fall under the Priority Watch List are those that do not provide an adequate level of IPR protection or enforcement, or market access for persons relying on intellectual property protection. Trading partners on the Watch List merit bilateral attention to address IPR problems. Certain other countries with serious IP-related problems are subject to another part of the statute, Section 306 monitoring, because of previous bilateral agreements reached with the United States to address specific problems raised in earlier reports.

The interagency Trade Policy Staff Committee that advises USTR on the implementation of Special 301 obtains information from the private sector, U.S. embassies, the United States' trading partners, and the National Trade Estimates report.

## **OUT-OF-CYCLE REVIEW RESULTS**

### **CHINA**

In its 2004 Special 301 report, USTR announced that it would conduct an out-of-cycle review (OCR) in early 2005 to evaluate China's implementation of its commitments made at the 15th annual meeting of the Joint Commission on Commerce and Trade (JCCT) in April 2004. During the OCR process, USTR requested detailed information on the prevalence of IPR infringement in China and the strengths and weaknesses of China's IPR protection and enforcement regimes. USTR also engaged with dozens of rights holders, interested members of the public and with Congress. This section contains USTR's analysis, findings and recommendations.

The United States recognizes that China, under the leadership of Vice Premier Wu Yi, has expended significant effort to improve the protection of IPR in China. Indeed, these efforts have resulted in progress in some areas. The United States remains gravely concerned, however, that China has not resolved critical deficiencies in IPR protection and enforcement and, as a result, infringements remain at epidemic levels. Accordingly, the United States concludes that there has not been a significant reduction in IPR infringements throughout China, as it committed to do at the April 2004 JCCT. Therefore, the United States will:

- Work with U.S. industry and other stakeholders with an eye toward utilizing WTO procedures to bring China into compliance with its WTO TRIPS obligations, particularly those requiring transparency and a criminal IPR enforcement system with deterrent effect.
- Invoke the transparency provisions of the WTO TRIPS Agreement, which will require China to produce detailed documentation on certain aspects of IPR enforcement that affects U.S. rights under the TRIPS Agreement.
- Elevate China onto the Priority Watch List on the basis of serious concerns about China's compliance with its WTO TRIPS obligations and commitments China made at the April 2004 JCCT to achieve a significant reduction in IPR infringement throughout China, and make progress in other areas.
- Maintain Section 306 monitoring of China's implementation of its 1992 and 1995 bilateral agreements with the United States (including additional commitments made in 1996).
- Use the JCCT, including the IPR Working Group, to secure new, specific commitments concerning additional actions that China will take to significantly improve IPR protection and enforcement, particularly over the next quarter. China's fulfillment of these commitments will be a centerpiece of the 2005 JCCT.

China agreed at the April 2004 JCCT to take the following specific steps:

- Significantly reduce IPR infringement levels across the country;

- Subject a greater range of violations to criminal investigation and penalties, and apply criminal sanctions to the import, export, storage and distribution of pirated and counterfeit products and to on-line piracy;
- Crack down on IPR violators through nationwide enforcement actions, increased customs enforcement actions and making it easier for rights holders to secure effective border enforcement;
- Improve protection of electronic works by ratifying and implementing the WIPO Internet Treaties as soon as possible, and by extending to local governments the existing ban on the use of pirated software by the central government and provincial agencies;
- Launch a national IPR education campaign; and
- Establish an IPR working group under the JCCT to consult and cooperate with the United States on the full range of IPR issues.

During the OCR, USTR systematically collected and evaluated facts relevant to assessing China's progress in fulfilling its JCCT commitments, its WTO obligations and its commitments under the 1992 and 1995 bilateral agreements with the United States (including additional commitments made in 1996). Through a letter and questionnaire to U.S. industry groups and a subsequent Federal Register Notice, USTR requested detailed information on the prevalence of IPR infringement in China generally, as well as on individual cases of IPR infringement. USTR received 34 submissions from industry, a number of which were very useful in USTR's review.

USTR has now completed the OCR, and is reporting the results in conjunction with this year's annual Special 301 review for China.

### **Infringement Levels Remain Unacceptably High**

China's inadequate IPR enforcement is resulting in infringement levels at 90 percent or above for virtually every form of intellectual property, according to the OCR submissions that USTR received.

Overall piracy rates in China have not declined significantly since WTO accession, and in some sectors have increased from already extremely high levels. OCR submissions report estimated U.S. losses due to piracy of copyrighted materials alone ranging between \$2.5 billion and \$3.8 billion annually. Internet piracy is quickly becoming the number one threat to the copyright industry according to OCR submissions. End-user piracy of business software and other copyright materials, such as books and journals, remains a key concern.

OCR submissions also confirm that China has not yet achieved a significant reduction in trademark counterfeiting. On the contrary, in 2004, the value of Chinese counterfeits coming into U.S. markets seized by the United States increased 47 percent from US\$94 million to US\$134 million. These seizures continued to account for 67 percent of all U.S. Customs' IPR seizures in 2004. China's counterfeit products threaten public health and safety in the United



States, in China and throughout the world. Batteries, pharmaceuticals, auto parts, industrial equipment and many other counterfeit products from China come to our shores. The OCR submissions aver, for example, that foreign pharmaceutical companies lost 10-15 percent of annual revenues in China due to increased counterfeiting.

### **Evaluation of TRIPS Obligations and 2004 JCCT Commitments**

#### **Transparency**

Article 63 of the TRIPS Agreement requires laws, regulations and final judicial decisions and administrative rulings of general application pertaining to IPR infringement be made publicly available to rights holders. Despite this requirement, lack of transparent information on IPR infringement levels and enforcement activities in China continues to be an acute problem. Several OCR submissions express concern regarding the Chinese Government's unwillingness to provide sufficiently detailed enforcement information. For example, one industry group observed that "[a]lthough Chinese authorities have undertaken some administrative enforcement actions against pirates, the Government's refusal to share information about ... the ultimate outcomes of these actions makes it very difficult for rights holders to assess the deterrent impact of China's enforcement efforts."

Transparency in rulemaking is also a continuing problem. Government entities responsible for drafting rules often refuse to make drafts widely available for public comment, and instead limit their "consultations" to pre-selected industry and trade associations. A prime example is China's drafting of the criminal judicial interpretation. During the 2003 Transitional Review of China's WTO/TRIPS compliance, China pledged to increase transparency by making draft judicial interpretations on IPR matters available for public comment. Despite this pledge made in Geneva and numerous requests from the United States and rights holders, China refused to release a draft of its December 2004 judicial interpretation for public comment. In addition, guidelines for the examination of patents and trademarks are not publicly available, and numerous local rules, such as those governing trade secrets, are inconsistent with national law, regulations or rules, resulting in uncertainty and confusion for rights holders.

#### **Criminal Enforcement**

Article 61 of the TRIPS Agreement requires a criminal IPR enforcement system with deterrent effect. Presently, however, criminal enforcement in China has not demonstrated any deterrent effect on infringers. China's authorities have pursued criminal prosecutions in a relatively small number of cases, notwithstanding China's commitment to the United States to impose more criminal penalties on the range of counterfeiting and piracy activities. While the number of criminal trademark prosecutions appears to be increasing, we have reports of very few, if any, criminal copyright prosecutions. When criminal prosecutions are pursued, a lack of transparency makes it difficult to ascertain whether they resulted in convictions and, if so, what penalties were imposed.

The Supreme People's Court and Supreme People's Procuratorate (SPP) issued a new judicial interpretation (JI) in December 2004 redefining the criteria for (1) commencing prosecutions and

(2) imposing criminal convictions. The JI's key improvements and deficiencies include the following:

- Improvements – (a) lowers the criminal thresholds; (b) applies accomplice liability to importers, exporters, landlords and others who provide assistance to infringers; (c) permits goods produced in factories and/or kept in warehouses to be included in sales calculations; (d) authorizes using the number of illegally duplicated disks or advertising revenue for Internet infringements to satisfy the “for profit” requirement; and (e) expands the statutory definition of an infringing trademark.
- Deficiencies – (a) deletes special liability provisions for repeat administrative offenders (the “three strike rule”), dealers in counterfeit products that threaten public safety, and infringers of well-known trademarks; (b) determines whether criminal thresholds are met using the price of infringing goods rather than the price of legitimate goods; (c) criminalizes copyright infringements (including online piracy) only if undertaken to make a profit; (d) fails to independently criminalize the export of infringing goods; (e) fails to criminalize the unauthorized rental, translation, public performance, broadcasting, adaptation and “bootlegging” of performances, even when done “on a commercial scale;” (f) fails to address software end-user piracy; and (g) maintains thresholds three-times higher for units than for individuals.

The issuance of the JI and many of its provisions do signal top government and judicial level willingness to commit to addressing counterfeiting and piracy problems. The United States believes, however, that the JI did not go far enough to be an effective deterrent. China's efforts to draft a JI that would “increase penalties for IPR violations by subjecting a greater range of violations to criminal investigation, by applying criminal sanctions to import and export stages, storage and distribution of infringing products, and by applying criminal sanctions to online piracy,” were hampered by institutional differences and the need to accommodate competing domestic interests. Had China made drafts of the JI widely available for public comment and consulted with the United States as requested, at least some of the deficiencies noted above could have been avoided. The United States will examine closely China's implementation of the JI to determine whether its application addresses its underlying deficiencies and actually deters counterfeiting and piracy.

With regard to Internet piracy in particular, the JI provides that: “Distributing a written work, musical work, motion picture, television program or other visual work, computer software or other works to the public by information network” falls under the definition of ‘reproducing and distributing’ stipulated in Article 217 of the Criminal Law.” While this is a positive step, service providers are still not held liable for infringing material hosted on their networks and the profit motive requirement of the copyright thresholds may seriously hinder efforts to actually impose criminal liability.

### Nationwide Crackdowns and Customs Enforcement

*Crackdowns:* Although China's central Government has made largely satisfactory progress in bringing China's IPR laws and regulations into line with China's WTO commitments,

enforcement continues to be seriously inadequate. In 2004, IPR infringement continued to affect products, brands and technologies from a wide range of industries, including films, music, publishing, software, pharmaceuticals, chemicals, information technology, textile fabrics and floor coverings, consumer goods, electrical equipment, automotive parts and industrial products, among many others. Rights holders report that enforcement efforts, particularly at the local level, are hampered by poor coordination among Chinese Government ministries and agencies, local protectionism and corruption, high thresholds for initiating investigations and prosecuting cases, lack of training, and inadequate and non-transparent processes.

Articles 41 and 61 of the TRIPS Agreement require effective and deterrent IPR enforcement. Consensus exists among rights holders, however, that China's current IPR system relies too heavily on enforcement by administrative authorities and is non-deterrent. Dissatisfaction with the number and substance of investigations, prosecutions, and convictions last year by local police is widespread.

In August 2004, pursuant to China's JCCT commitments, the State Council announced a year-long national campaign to crack down on IPR infringements in sectors where trademark counterfeiting and copyright infringement are concentrated, including import and export activities, trade fairs and exhibitions, distribution and wholesale markets, brand name processing and publishing. On March 31, 2005 Vice Premier Wu Yi extended this campaign until the end of 2005. This next phase will focus on food and pharmaceutical trademark and well-known mark infringements, and target street vendors of illegal publications, audio-visual products and software.

Industry confirms that these campaigns have in fact resulted in increased seizures of infringing materials. What happens to seized product, however, is not transparent. We continue to hear reports of seized counterfeit and pirated goods being auctioned or otherwise returned to the channels of commerce. It is also clear that cases subsequently brought by the administrative authorities have resulted in extremely low fines.

The lack of deterrence from the fines is compounded by the fact that there has been a steady decline in the number of cases that administrative authorities forward to the Ministry of Public Security for criminal investigation, even for commercial-scale counterfeiting or piracy. According to Chinese Government statistics, there were 86 transfers in 2001; 59 in 2002; 45 in 2003; and only 14 in the first half of 2004. As a result, infringers are not deterred by the risk of criminal prosecution and serving jail time. They simply consider the seizures and fines to be a cost of doing business, and are usually able to resume their operations without much difficulty. Despite receiving good cooperation from some local administrative authorities, some rights holders reported a decrease in the number of seizures of infringing products in 2004 – due to smarter pirates, not decreasing levels of infringement.

A number of U.S. right holder groups have recently stepped up efforts to monitor IPR enforcement in China and its results in the Chinese market. The United States welcomes these initiatives and urges their continuation. By promoting transparency, these private sector initiatives enhance government-to-government cooperation toward achieving effective IPR enforcement.

*Customs/Administrative Enforcement:* The export of infringing products from China is of grave concern worldwide. At the U.S. border alone, counterfeit and pirated imports from China account for 67 percent of seizures by U.S. Customs and Border Protection, and the value of the products seized rose by 47 percent in 2004. Seizures by Chinese customs authorities are down, despite China's JCCT commitment to increase customs enforcement actions. Rights holders report finding infringing products of Chinese origin in most major world markets, but being unable to secure customs seizures in China. This raises serious concern.

Following China's April 2004 JCCT commitments, China's General Administration of Customs (GAC) issued new regulations and implementing rules intended to strengthen border enforcement and to make it easier for rights holders to secure effective enforcement at the border. The new regulations outline GAC's duties and provide guidance on the implementation of the customs IPR recordal mechanism, extend the term of IPR recordations from seven to ten years, and lower the cap on the security bonds required from rights holders seeking the seizure of allegedly infringing goods. In a significant step backward, however, the new rules no longer expressly authorize customs authorities to levy administrative fines on companies engaged in trading counterfeit or pirated goods and reduce the fines that Customs authorities can impose from 100 percent to 30 percent of the value of the goods. Proposed amendments to China's Foreign Trade Law also fail to address this important issue. In addition, the new measures fail to address the transfer of cases for criminal investigation and prosecution and do not authorize nationwide bonding to cover China's more than 100 customs ports of entry. Disposal of confiscated goods also remains a problem under the regulations, which allow for auction rather than mandating destruction of seized goods.

*Civil Enforcement:* In part because of the ineffectiveness of the administrative and criminal enforcement systems in China, there has been an increase in the number of civil actions seeking monetary damages or injunctive relief. Most of these actions have been brought by Chinese rights holders, although foreign rights holders are increasingly turning to the civil system for redress. While seeing some success, we continue to hear complaints of a lack of consistent, uniform and fair enforcement of China's IPR laws and regulations in the civil courts. Litigants have found that most judges lack necessary technical training, court rules regarding evidence, expert witnesses, and protection of confidential information are vague or ineffective, and the costs of investigation and bringing cases are prohibitively high. In the patent area, where civil enforcement is of particular importance, the process is inefficient and unpredictable. A single case can take four to seven years to complete.

#### Protection of Electronic Works, WIPO Treaty Accession and Government Use of Legitimate Software

Copyright infringement on the Internet is a growing phenomenon in China because of loopholes in existing regulations and implementing rules. Despite its JCCT commitment, China still has not acceded to the WIPO Internet Treaties. China's current regulations, implementing rules and judicial interpretations do increasingly address copyright issues related to the Internet. China is currently drafting additional Internet-related regulations.

Widespread use of pirated software in government offices continues. Consistent with China's April 2004 JCCT commitments, Vice Premier Wu Yi directed that by the end of 2004, all government institutions at all levels would use only legal software. While the local governments of Shanghai, Beijing, Guangzhou, Zhejiang and several other provinces and municipalities have instituted measures requiring use of only legal software, this does not satisfy China's commitment to ensure that all government agencies at all levels use only legal software.

#### Public Awareness/Education

In 2004, China launched a national public awareness campaign as part of its JCCT commitment to educate the Chinese public on IPR protection. For example, the State Intellectual Property Office (SIPO) introduced a television program, "Intellectual Fortune," which is broadcast in 20 provinces nationwide. In April 2004, SIPO began publishing an English language insert in the China Daily English-language newspaper on intellectual property. China IPR trade journals also routinely report on specific efforts targeting students and industries. In February 2005, the National Copyright Administration hosted a nationally broadcast anti-piracy concert at Beijing Capital Stadium, with a television audience that was estimated by its sponsors at 500 million. It is too early to tell what the long-term implications of this campaign will be.

#### IPR Working Group

USTR, working closely with the U.S. Patent and Trademark Office, is preparing a detailed work plan for obtaining tangible results in the specific areas noted below, and plans to hold the Working Group's first meeting in Washington in early summer 2005.

#### Patent Developments

While China's patent laws are largely compliant with the TRIPS Agreement, OCR submissions reveal that the narrow scope of patentable subject matter under Chinese law makes patents for transgenic plants and animals virtually unobtainable. A lack of clarity in laws involving generic drug patent infringement is contributing to the continued growth of counterfeit drugs. The State Food and Drug Administration has now provided in its new drug registration regulations coordination mechanisms between the health authority and patent office to prevent unauthorized registrations of patent-infringing products. However, we have no reliable data on how well these new regulations work.

In addition, OCR submissions report that China has yet to implement any meaningful data protections for pharmaceutical products, as required by Article 39.1 of the TRIPS Agreement.

#### OCR/Special 301 Determination

The United States reaffirms its appreciation for the efforts of Vice Premier Wu Yi and the progress that has been made in some areas. Nevertheless, based upon the information received during the OCR, the United States concludes that China has failed to significantly reduce IPR infringement levels, as required under the JCCT. Consequently:

- First, the Administration will use WTO instruments whenever appropriate to address our concerns regarding the unacceptable levels of counterfeiting and piracy in China. We agree with the many industries and companies that have identified lack of transparency as a serious barrier to a more complete understanding of key deficiencies in China's IPR enforcement system. Accordingly, we will invoke the transparency provisions of the WTO TRIPS Agreement to request that China provide detailed documentation on certain aspects of IPR enforcement that affect U.S. rights under the TRIPS Agreement. We will, for example, be seeking information on criminal and administrative penalties actually imposed. Statistics provided by China's central Government list numbers of cases, but often lack specificity on the legal basis for those cases and other important details. We look forward to China's complete response.
- Second, USTR is elevating China onto the Priority Watch List on the basis of serious concerns about compliance with WTO TRIPS obligations related to IPR enforcement, and the commitments China made to the United States at the April 2004 meeting of the JCCT to achieve a significant reduction in IPR infringement, and make progress in other areas. This marks the first time that China has been elevated to the Priority Watch List on the basis of WTO TRIPS or JCCT-related concerns. The United States will also maintain Section 306 monitoring of China's implementation of its 1992 and 1995 bilateral agreements with the United States (including additional commitments made in 1996).
- Third, the United States will use the JCCT and IPR Working Group to secure new, specific commitments concerning additional actions that China will take that result in significant improvements in IPR protection and enforcement, particularly over the next quarter. We will seek tangible results in areas of weakness identified in the OCR and of key concern to U.S. persons that rely upon intellectual property protection.

### Tangible Results

China must fulfill its 2004 JCCT commitments to the United States. Based upon deficiencies identified during the OCR, China must:

- Undertake additional aggressive action to significantly reduce IPR infringement levels.
- Show demonstrable results in at least the following areas:
  - Demonstrate a significant increase in the number of criminal IPR investigations, prosecutions, convictions and deterrent, proportionate sentences involving U.S./foreign rights holders, especially including but not limited to criminal copyright cases.
  - Remove the market advantages currently enjoyed by pirated and counterfeited goods resulting from market access restrictions and administrative delays so as to facilitate increased sales of the legitimate products.

- Make administrative IPR enforcement actions deterrent.
- Demonstrate a significant decline in exports of IPR infringing goods.
- Combat copyright and trademark infringing activities, including Internet piracy, through specific actions.
- Make publicly available case rulings and IPR-related statistical data, including data on government compliance with software copyright licensing, and on administrative and judicial decisions, including penalties imposed.

The United States will work through the JCCT IPR Working Group, particularly over the next quarter, to identify specific action items for China to undertake in each of these areas, and will make fulfillment of these undertakings a centerpiece of the 2005 JCCT meetings.

## **PRIORITY FOREIGN COUNTRY**

### **UKRAINE**

The United States withdrew Ukraine's benefits under the Generalized System of Preferences (GSP) program in August 2001 and imposed \$75 million worth of sanctions on Ukrainian imports in January 2002. These sanctions remain in effect based on the repeated failure of the Government of Ukraine to enact and implement adequate optical disc media licensing legislation in order to comply with the June 2000 U.S.-Ukraine Joint Action Plan to Combat Optical Media Piracy. The Ukrainian Government has drafted amendments to the existing Optical Disc Licensing Law to address inadequacies, but Ukraine's Rada has failed to pass these amendments on several occasions. The United States notes with optimism that Ukraine's Rada currently is undertaking efforts to pass these amendments. However, until such amendments are passed, Ukraine's law lacks adequate provisions to prevent unauthorized optical media production and distribution. Ukraine is also a major transshipment point and storage location for illegal optical media produced in Russia and elsewhere. Ukraine's border enforcement efforts remain weak and criminal penalties for unauthorized production and export of CDs and CD-ROMs are not significant enough to act as an effective deterrent. As a result, there continue to be extremely high levels of piracy and substantial losses to U.S. industry. Trademark counterfeiting is also a serious problem, and the U.S. trademark industry remains concerned over the lack of cooperation by enforcement officials in combating counterfeiting activities. The United States urges the Ukrainian Government to pass needed amendments to its optical media law in the near term and to enforce that law aggressively to significantly reduce high levels of piracy and exports of pirate product. The United States is announcing that a Special 301 out-of-cycle review will be commenced in 2005 to monitor Ukraine's progress in passing amendments to its optical media law, implementing the new law, and deterring optical media piracy through adequate enforcement.



## **SECTION 306**

### **PARAGUAY**

We commend the significant efforts of the Duarte Administration to improve the protection of intellectual property. For example, the Ministry of Industry and Commerce (MIC) has been cooperating with industry to share data on importers and shipments of optical media. The MIC also now requires importers to provide copies of their sales receipts identifying the buyers. The MIC's documentary requirements have led to the closure of more than 50 importing companies. The MIC created the Specialized Enforcement Unit, which has participated in numerous important seizures. The USTR identified Paraguay as a Priority Foreign Country in January 1998 as part of a Special 301 out-of-cycle review. The subsequent Special 301 investigation terminated with the signing of a comprehensive Memorandum of Understanding (MOU) on the protection of intellectual property in 1998. After that MOU expired, the U.S. and Paraguay signed a new MOU in March 2004, which will terminate on December 31, 2005. Paraguay has been under Section 306 monitoring since the signing of the 1998 MOU, and in 2005 the United States will continue to monitor Paraguay under Section 306. Paraguay continues, however, to have problems providing effective protection to copyrights and trademarks, with respect to internal enforcement, border enforcement and low penalties in the current laws. We remain concerned over several issues, including: persistent problems with enforcement due to porous borders; the involvement of organized crime in piracy and counterfeiting operations; ineffective prosecutions for IPR infringements; and the lack of consistent deterrent sentences, including imprisonment, in court cases. The United States also has concerns regarding data protection and a 2004 patent resolution, and will continue to work with Paraguay to address these IPR concerns.

## **PRIORITY WATCH LIST**

### **ARGENTINA**

Although there have been some improvements in intellectual property protection in Argentina, significant problems remain that warrant keeping Argentina on the Priority Watch List for 2005. The Government of Argentina amended its patent law to provide, among other things, process patent protection. This new patent law, which has been in effect since January 2004, implements the May 2002 U.S.-Argentina agreement. Argentina has also put in place fast-track procedures for patent applications. However, Argentina's overall copyright, patent, and data protection regimes do not appear to meet international standards. Copyright piracy remains a significant problem in numerous industry sectors, including audiovisual (pirated DVD copies of movies and recordable CDs (CD-Rs)), sound recordings (pirated CD-Rs), entertainment software (pirated videogames), business software, and book publishing. Although the Argentine Government initiated some IPR enforcement actions during 2004, the following enforcement problems still exist: lack of deterrent criminal penalties in commercial piracy cases, delays in bringing and completing criminal and civil infringement cases, ineffective border controls, and lack of deterrent civil damages. In the area of agricultural biotechnology products, unauthorized use of protected seed varieties remains a problem. The May 2002 U.S.-Argentina agreement is a partial settlement of a WTO dispute settlement case initiated by the United States concerning Argentina's implementation of various TRIPS obligations. The important issue of data protection remains unresolved. Argentina still does not provide protection from unfair commercial use for confidential data submitted by research-based pharmaceutical companies. The United States also urges Argentina to implement an effective coordination system between the health agency and patent office to prevent the infringement of patented pharmaceutical products. USTR will continue to monitor Argentina's efforts to address these concerns, as well as its compliance with the commitments made under the May 2002 agreement.

### **BRAZIL**

Brazil made some improvements to its intellectual property system in recent months, including the adoption of a National Action Plan by Brazil's National Council to Combat Piracy and Intellectual Property Crimes, as well as successes in enforcement along its border with Paraguay. Despite these improvements, however, high levels of piracy still exist and warrant Brazil's continued placement on the Priority Watch List in 2005. Brazil is one of the largest global markets for legitimate copyright products, but also is one of the world's largest markets for pirated products. Optical media and Internet piracy rates are increasing and the U.S. copyright industry estimates that losses in Brazil exceeded \$931 million in 2004. Despite having adopted modern copyright legislation, Brazil has not undertaken adequate enforcement actions against copyright piracy. Criminal enforcement has not been sufficient or effective in deterring these illegal activities. Furthermore, although the Brazilian police conducted a substantial number of raids in 2004, very few resulted in criminal prosecutions and convictions. Ineffective border enforcement has failed to stop an influx of pirate and counterfeit goods, particularly in the Manaus Free Trade Zone in Brazil. In addition, Brazil has not made significant progress in processing its backlog of pending patent applications, due in part to a requirement that the health regulatory agency issue approval before pharmaceutical patents are granted by the Brazilian patent office. We will continue to monitor Brazil's progress, including through the ongoing GSP review which has been extended to September 30, 2005, in order to allow time for the new

National Action Plan to become effective in enforcing copyrights and reducing piracy. The extension of the review was a result of some initial positive steps taken by the Brazilian Government, as well as USTR consultations with U.S. copyright stakeholders. The focus of the extended review will be on implementation and enforcement of both existing laws and recently adopted measures. The Administration looks to the Government of Brazil to achieve and demonstrate concrete progress in reducing unacceptable levels of copyright piracy, particularly through increased prosecutions and criminal convictions.

## **EGYPT**

Egypt was elevated from the Watch List to the Priority Watch List in 2004 for shortcomings related to unauthorized marketing approvals granted for patent-infringing pharmaceutical products, deficiencies in Egypt's IPR enforcement regimes for copyrights and trademarks, and problems with its judicial system. Because little progress has been made on these issues during the past year, Egypt will be maintained on the Priority Watch List in 2005. We are concerned over reported actions by the Ministry of Health that appear to undermine Egypt's obligations under TRIPS to protect test data submitted for marketing approval against unfair commercial use for pharmaceutical and agricultural chemical products. In addition, we continue to be concerned about the lack of coordination between Egypt's health authorities and patent office that would prevent the unauthorized registration of patent-infringing products. The U.S. copyright industry continues to note its concern over deficiencies in implementing regulations for Egypt's copyright law. Egypt improved its copyright enforcement efforts slightly for some industries, although the U.S. copyright industry estimates its losses to be \$72.5 million in Egypt for 2004. Copyright piracy remains high for book publishing, as well as for entertainment and business software. Although piracy rates decreased slightly in 2004 in the music industry due to increased police activity, there are insufficient improvements in overall copyright enforcement. Copyright enforcement is further impaired by a court system in which copyright and trademark cases continue to move slowly, collection of judgments is difficult, and transparency appears to be lacking. Efforts by Egypt to address these problems and to improve its IPR regime will continue to play an important role in the expansion of trade and investment ties with the United States.

## **INDIA**

While India has improved its IPR regime in some respects, protection of intellectual property in many areas remains weak due in part to inadequate laws and to ineffective enforcement. Consequently, India will remain on this year's Priority Watch List. We urge India to improve its IPR regime with respect to protecting undisclosed test data against unfair commercial use for pharmaceutical and agricultural chemical products, as well as for copyrights, trademarks, and patents. India took a significant positive step toward strengthening patent protection when it promulgated a temporary Patent Amendment Ordinance at the end of 2004 and then passed permanent legislation in early 2005. However, the U.S. pharmaceutical industry reports shortcomings in this patent legislation that we hope India will correct. Most notably, the new law does not permit holders of patents that will issue from "mailbox" applications to enforce their rights with respect to generic copies that continue to be marketed on the date that the patent is granted. The extent to which India's new patent legislation satisfies India's TRIPS commitments is still under review and will depend, in part, on its implementation. Thus, we will monitor closely India's implementation of the patent amendment. India has yet to implement a TRIPS-compliant regulation to protect confidential test and other data submitted by innovative

pharmaceutical and agricultural chemical companies seeking market approval for their products against unfair commercial use. In addition, copyright piracy is rampant, and the U.S. copyright industry estimates that lost sales resulting from piracy in India of U.S. motion pictures, sound recordings, musical compositions, computer programs, and books totaled approximately \$500 million in 2004. India is not a party to the WIPO Internet Treaties. We understand, however, that India is in the process of discussing amendments to the Indian Copyright Act which would enable India to implement these treaties. India has not adopted an optical disc law to address optical media piracy, and cable television piracy continues to be a significant problem. Although the Government of India has pledged to improve its trademark regime, protection of foreign trademarks remains difficult due to procedural barriers and delays. Areas in need of improvement include national treatment for the use of trademarks owned by foreign proprietors, statutory protection of service marks, and clarification of the conditions that justify the cancellation of a mark due to non-use. India's criminal IPR enforcement regime remains weak in multiple areas, including border protection against counterfeit and pirated goods, police action against pirates, following up raids by obtaining convictions for copyright and trademark infringement, courts reaching dispositions and imposing deterrent sentences, and delays in court dispositions. We hope that India will address these issues during the coming year and thereby strengthen its IPR regime.

## **INDONESIA**

Indonesia will remain on the Priority Watch List for 2005, and the United States will conduct an out-of-cycle review to monitor Indonesia's progress on IPR issues. Indonesia took steps in 2004 to strengthen its IPR protection regime. Notably, Indonesia passed Optical Disc Regulations in 2004 that took effect in April 2005 and demonstrate Indonesia's commitment on paper to improving its IPR regime. The U.S. copyright and trademark industries report that serious concerns remain, however, over numerous issues, including: lack of effective IPR enforcement; the adequacy of the new regulations to reduce the production, distribution, and export of pirated optical media products; trademark infringement; and deficiencies in Indonesia's judicial system. Indonesia carried out some raids against retail outlets for pirate optical media products in 2004, but the U.S. copyright industry reported that enforcement and prosecution of IPR violations remained insufficient and non-deterrent. Pirate optical media products, including CDs, VCDs, DVDs and CD-ROMs, still dominate Indonesia's market. The U.S. copyright industry estimated losses in Indonesia of approximately \$197.5 million in 2004. A number of companies continue to report trademark infringement involving a wide range of products, including information technology products, clothing, and soft drinks, among others. In addition to the out-of-cycle review, the United States will continue to use our bilateral Trade and Investment Framework Agreement (TIFA) to work with Indonesia to take the additional measures necessary to develop and implement a robust and effective IPR regime.

## **ISRAEL**

Over the last year, the United States and Israel engaged in extensive efforts to bridge differences on key IP issues. While progress was made in some areas, Israel's efforts to address its lack of protection against unfair commercial use for proprietary test data fell significantly short of responding to U.S. concerns. In March 2005, Israel's Knesset approved legislation on data protection, proposed by the Israeli Government, which fails to provide OECD-level protection against unfair commercial use for confidential test data submitted by innovator pharmaceutical

manufacturers. Compounding U.S. concerns, the Israeli Government drafted separate legislation that would curtail existing pharmaceutical patent term adjustments granted to compensate for delays in obtaining regulatory approval of a drug. Industry also has raised concerns that the administrative requirements in the current draft legislation would make it very difficult for U.S. companies to obtain any patent term extension. Based on Israel's implementation of an inadequate data protection regime, as well as its apparent intention to pass legislation to weaken patent term adjustments, Israel is being elevated to the Priority Watch List. The United States is also concerned about the continuing problems experienced by U.S. biotechnology firms in Israel. These firms suffer from a lack of adequate protection for their intellectual property in Israel, due to an onerous patent system that allows competitors to delay the granting of patent rights through open-ended, pre-grant opposition proceedings, as well as weak protection of proprietary data against unfair commercial use.

Israel made progress by giving written assurances that it will continue to provide national treatment for U.S. rights holders in sound recordings. In addition, the U.S. copyright and trademark industries report a more serious treatment of IPR violations by Israeli courts and continuing efforts by Israeli authorities to improve enforcement of copyrights and trademarks. However, the U.S. copyright industry notes that the persistence of a significant level of piracy, such as the “burning” of copyright-infringing content onto CD-Rs and DVD-Rs, suggests that additional IPR enforcement resources are needed. The United States hopes to see continued progress on copyright and trademark enforcement in Israel and will continue to urge Israel to improve its data protection regime in order to promote increased bilateral trade and investment in the field of pharmaceuticals and other knowledge-based sectors.

#### **KUWAIT**

Kuwait is being maintained on the Priority Watch List this year due to its high rates of copyright piracy and its lack of progress in amending its copyright law to meet international obligations. Furthermore, Kuwait has not yet fully implemented the 2002 work plan that outlined the steps it would take to increase IPR enforcement. In 2004, IPR enforcement efforts remained insufficient and penalties for infringement remained inadequate to deter potential offenders. Kuwait proposed a draft copyright law in 2004, which has not yet been passed by Kuwait's legislature. The U.S. copyright industry reports that Kuwait continues to have high levels of retail optical disc piracy, as well as problems with corporate end-user software piracy, cable piracy, and Internet piracy. We urge Kuwait to improve the situation by making public declarations at the highest level that piracy in Kuwait will not be tolerated, increasing the frequency of raids on suspected infringers, prosecuting offenders, imposing deterrent sentences, publishing the outcomes of inspection raids in order to deter others, and amending its copyright law in the near future to correct its deficiencies. Kuwait has made some progress, such as Kuwait Customs' creation of a special IPR unit in April 2004 that began taking some enforcement actions. The Ministry of Commerce also stepped up enforcement efforts in late 2004. Although these are positive steps, we hope that key ministries with IPR enforcement responsibilities, including the Ministry of Information, will take further measures to combat IPR infringement over the long term. We will continue to address these issues under the U.S.-Kuwait Trade and Investment Framework Agreement signed in February 2004.

#### **LEBANON**

We commend the Lebanese Government for some recent steps that it has taken to begin to address longstanding IPR problems, including a large-scale raid on pirated optical disc warehouses that resulted in the imposition of jail sentences for the warehouse owners, other enforcement raids against pirate vendors, and efforts by Lebanese Customs to carry out ex officio inspections and seizures along the borders. However, due to continuing problems with rampant cable piracy, retail piracy of pre-recorded optical discs, computer software piracy, and pharmaceutical counterfeiting, Lebanon will be kept on the Priority Watch List for 2005. The Lebanese Government issued new requirements for registering pharmaceutical products, but the U.S. pharmaceutical industry reports continuing problems with the Lebanese Ministry of Health approving marketing registrations of unauthorized copies of pharmaceuticals patented in Lebanon. We encourage Lebanon to strengthen its data protection provisions. Counterfeiting of trademarked goods (including pharmaceutical products) continues with little apparent effort by the Government of Lebanon to deter this activity. Lebanon continues to face problems in providing adequate and effective intellectual property protection, and the United States urges Lebanon to address these issues in the near future. Problems persist with the widespread availability of pirated optical discs and rampant cable piracy. According to the U.S. copyright industry, well over 80 percent of Lebanon's cable subscribers view pirated content, one of the highest rates in the world. We encourage Lebanon to improve its judicial system and to commit its resources to improving IPR enforcement. Lebanon has neither acceded to nor fully implemented the latest text of the Berne Convention or the WIPO Internet Treaties. We urge the Lebanese Government to continue its efforts to address these problems and to ratify and implement the WIPO Internet Treaties soon. The United States will monitor these efforts closely with the hope an improved IPR regime will benefit Lebanon's economy and our bilateral trade relationship. We continue to review Lebanon under the Generalized System of Preferences (GSP) for inadequate copyright protection.

## **PAKISTAN**

Pakistan made some progress in IPR issues during the past year, including Pakistani Customs' seizures of numerous pirated discs destined for export. However, because the overall piracy and counterfeiting problems in Pakistan have not improved significantly over the past year, we are maintaining Pakistan on the Priority Watch List in 2005. In addition, we will continue a review of Pakistan under the Generalized System of Preferences (GSP) for inadequate copyright protection. According to the U.S. copyright industry, Pakistan is one of the world's leading producers/exporters of pirated optical media of copyrighted sound recordings, motion pictures, business software, and published materials. The vast majority of pirated goods exported from Pakistan consisted of apparel, pharmaceuticals with counterfeit trademarks, or optical media products. We recognize that Pakistan took some initial steps to address these problems, and we are encouraged by reports in April 2005 that Pakistan has proposed legislation to form the long-awaited Pakistan Intellectual Property Organization (PIPPO), which is designed to centralize enforcement. Despite these positive signals, the U.S. copyright industry is disappointed that Pakistan has not introduced effective optical media plant control measures, including the ability to track the movement of optical media production equipment and raw materials. Moreover, Pakistan has not compelled the use of source identification codes to address production of pirated CDs and CD-ROMs. Pakistani authorities neither conducted routine plant raids and seizures on a regular basis, nor have they imposed deterrent criminal penalties for organized manufacturing and distribution of pirated and counterfeit products. An example of Pakistan's ineffective IPR

enforcement occurred in 2004, when four optical disc plants closed voluntarily, but reopened when it became apparent that the Government of Pakistan did not intend to impose any penalties for continued activities related to piracy. Additional concerns include lack of protection against the unfair commercial use of data submitted for marketing approval of pharmaceutical and agricultural chemical products, lack of trademark enforcement, copyright piracy beyond optical media (e.g., book piracy), the emergence of pre-release sound recordings and motion pictures, and lax IPR enforcement overall. The United States also remains concerned over a 2002 ordinance that seriously undermined WTO-required improvements that Pakistan made to its patent law in 2000. The United States urges Pakistan to intensify its efforts to improve IPR protection and enforcement.

## **REPUBLIC OF THE PHILIPPINES**

The Philippines will remain on the Priority Watch List in 2005. USTR will conduct an out-of-cycle review to monitor progress on IPR issues and possibly to reassess the Philippines' placement on the Special 301 list. The Philippines made significant progress in 2004 which the U.S. copyright industry noted could lead, if continued, to the elimination of optical media piracy in the Philippines. These important improvements included the passage of the Optical Media Act in February 2004, the creation of the Optical Media Board, accession to the WIPO Internet Treaties, improved coordination of the groups responsible for IPR enforcement, and an increased number of raids of production facilities and retail establishments. The Philippines also implemented the Optical Media Act in early 2005, which should enable Philippine authorities to take decisive action against pirate optical media production facilities. We are encouraged by the notable single seizure of optical discs (over \$8 million worth of optical discs) in December 2004. However, despite these improvements, U.S. industry continues to raise serious concerns about high levels of copyright piracy and trademark counterfeiting, including book piracy, increasing levels of pirated optical media imported into the country, and pervasive end user software piracy. The U.S. copyright and trademark industries also report continued difficulty protecting their rights through the Philippine legal system due to low conviction rates and imposition of non-deterrent sentences. Trademark infringement in a variety of product lines also is widespread, with counterfeit merchandise openly available in both legitimate and illegitimate venues. The levels of illegal production and consumption of optical media remain consistently high. The U.S. copyright industry estimated its losses due to copyright piracy in the Philippines at \$139 million in 2004. Enforcement efforts such as raids and seizures often have only a temporary effect due to ineffective post-raid follow-up, including prosecution. The U.S. copyright industry reports that counterfeit goods from China, Malaysia, Hong Kong, and Thailand continue to enter the Philippines in large quantities due to weak IPR border enforcement. In response, the Bureau of Customs created a permanent IPR unit in September 2003 to investigate all shipments of counterfeit and pirated goods, but U.S. industry reports that this IPR unit has had inadequate staff and other resources since its inception, and thus has had minimal success. It appears that domestic enforcement in general suffers from lack of sufficient resources, training, and interagency coordination, which has led to ineffective post-raid management and a growing backlog of cases in the judicial system. We also urge the Philippine Government to implement copyright provisions to make its domestic law consistent with its obligations under the WIPO Internet Treaties, which it ratified in 2002. The United States will use the bilateral Trade and Investment Framework Agreement (TIFA) and the out-of-cycle review to assist the Government of Philippines with strengthening its IPR regime.

## **RUSSIA**

Despite some legislative improvements and increased engagement between the United States and Russia on IPR issues, certain aspects of Russia's IPR regime, including enforcement and data protection, appear to be inconsistent with Russia's obligations under the 1992 U.S.-Russian Federation Trade Agreement and thus would not conform to obligations which Russia needs to fulfill in order to join the WTO. For these reasons, Russia remains on the Priority Watch List in 2005. The United States will conduct an out-of-cycle review in 2005 to monitor progress by Russia on numerous IPR issues. As part of its effort to bring Russia's IPR regime into compliance with the obligations of the TRIPS Agreement, Russia amended its Copyright Law in 2004 to provide protection for pre-existing works and sound recordings. Russia has amended a number of other laws as well, including laws on patents, protection of layout designs for integrated circuits, plant varieties, and protection of computer software and databases. Although these amendments demonstrate Russia's commitment to strengthening its IPR regime at the legislative level, further legislative changes and enforcement improvements are necessary. For example, Russian law does not provide TRIPS-consistent protection against unfair commercial use of test data and other data submitted to obtain marketing approval for pharmaceutical and agricultural chemical products. Russian law also provides a reciprocity system for the protection of geographical indications that appears to be inconsistent with the TRIPS Agreement. Russia has not yet ratified the WIPO Internet Treaties and unfortunately has delayed implementation of a key provision (for certain digital transmissions) until September 2006. Enforcement in Russia remains weak and caused substantial losses for the U.S. copyright, trademark, and patent industries in the last year. Piracy in all copyright sectors continues unabated, and the U.S. copyright industry estimated losses of \$1.7 billion in 2004. The U.S. copyright industry reports that unauthorized domestic production of optical media has increased in Russia: there are over 30 known optical disc plants now in operation, approximately 21 of which are believed to be engaged at least part-time in the illegal production of pirated goods. The U.S. copyright industry reports the following levels of piracy: 66 percent in the recording industry, 80 percent in the motion picture industry, 87 percent for business software, and 73 percent for entertainment software. While there have been some improvements in anti-piracy actions by Russian law enforcement agencies, including an increased number of raids by police, overall IPR enforcement in Russia remains inadequate and piracy and counterfeiting levels continue to rise. Problematic IPR enforcement issues include the lack of an effective and deterrent criminal enforcement system (including many suspended sentences of major pirates), the lack of effective plant inspection and enforcement mechanisms; the lack of civil ex parte search procedures; an extremely porous border; delays in criminal prosecutions and adjudications; and infrequent destruction of seized pirate goods. Enforcement efforts in 2004 included several raids and seizures, including some at production facilities, but no plant licenses have been permanently suspended, plants have not ceased to operate, and the U.S. copyright industry estimates that 70 percent of seized pirated product was returned to the market. In addition, Internet piracy is increasing (industry reports that a Russian website is now the largest portal for pirate product in the world), and Russia has not taken decisive actions to combat this growing problem. We urge Russia to take immediate and effective steps to properly inspect all plants and to shut down illegal optical media plants and Internet sites, strengthen border enforcement, combat piracy and counterfeiting, and address deficiencies in its IPR laws. We will continue to monitor Russia's progress in bringing its IPR regime in line with international standards through the out-of-cycle



review, the ongoing GSP review that was initiated by USTR in 2001, and WTO accession discussions.

## **TURKEY**

Long-standing concerns over Turkey's lack of protection for confidential test data against unfair commercial use were noted in the 2004 Special 301 Report. In 2005, Turkey passed data protection legislation, but we are disappointed that it provides little effective protection for pharmaceutical products already on the market and limits protection for future pharmaceutical products. Due to these concerns over data protection, and the lack of data protection for agricultural chemicals, as well as other concerns over patent protection, copyright piracy, trademark counterfeiting, and IPR enforcement problems, Turkey remains on the Priority Watch List in 2005. We encourage Turkey to address the shortcomings in its data protection regime, as well as to implement a system of coordination between its regulatory health and patent regimes to prevent unauthorized registrations of patent-infringing products. With regard to copyright piracy, large-scale commercial photocopying of books and highly organized print piracy continue to be the chief problems in Turkey. During 2004, Turkey improved its copyright legislative regime and the U.S. copyright industry reported an almost immediate effect of the new law on retail street piracy. As a result of the new copyright legislation, major campaigns have been carried out against street piracy and courts have been willing to impose higher penalties. In the area of counterfeiting, the U.S. trademark industry notes its serious concern over shortcomings in Turkey's IPR enforcement against counterfeiting of apparel and designer brands and minimal deterrence of this activity by the Turkish court system. The United States hopes to see Turkey's continued progress on copyright, trademark and patent enforcement during the coming year, and will continue to monitor Turkey's progress in strengthening its IPR regime.

## **VENEZUELA**

Venezuela is being elevated to the Priority Watch List in 2005 due to the continuing deterioration of its already weak IPR regime and its declining commitment to IPR protection. The U.S. pharmaceutical industry continues to face significant losses in Venezuela, and reports that Venezuela is not providing protection to confidential test data against unfair commercial use for pharmaceutical and agricultural chemical products, despite its obligation to do so under the TRIPS Agreement. The U.S. pharmaceutical industry also notes that Venezuela has not issued any pharmaceutical patents since 2002, but instead it has continued to grant marketing approval for unauthorized domestic copies of pharmaceutical products patented in Venezuela. We are also concerned that the Venezuelan Intellectual Property Agency has opened an administrative process to revoke previously-granted patents. In the area of copyright, levels of piracy and contraband have grown increasingly problematic while government efforts toward deterrence and prosecution of these illegal activities remain minimal. This has resulted in the near extinction of the legitimate music market, which, coupled with film and software piracy, has led to \$92 million in estimated losses to the U.S. copyright industry in 2004. The U.S. copyright industry reports that proposed copyright legislation would severely undercut the current Venezuelan copyright law, as well as standards of protection under the Berne Convention, the TRIPS Agreement, and bilateral agreements. We urge the Venezuelan Government to take immediate action to improve IPR protection, particularly in the areas of protecting data against unfair commercial use for pharmaceutical and agricultural chemical products, copyright piracy and inadequate legislative proposals, trademark counterfeiting, and IPR enforcement.



## WATCH LIST

### **AZERBAIJAN**

Azerbaijan remains on the Watch List in 2005 because it has not addressed deficiencies in its IPR laws or fulfilled its IPR commitments under the 1995 U.S.-Azerbaijan Trade Agreement. For example, Azerbaijan's copyright law does not explicitly provide protection for pre-existing works or sound recordings. Neither the Criminal Code nor the Customs Code appear to provide for ex officio authority to commence criminal copyright cases and suspend the release of suspected infringing material at the border, and the Civil Code contains no explicit provision for civil ex parte search procedures. Further, while Azerbaijani law does provide criminal penalties for IPR violations, the U.S. copyright industry reports that there have been no criminal penalties or administrative sanctions imposed for copyright infringement in Azerbaijan this year. We encourage Azerbaijan to meet its obligations under the 1995 U.S.-Azerbaijan Trade Agreement, to accede to and fully implement the WIPO Internet Treaties, and to improve its enforcement efforts by providing for ex officio raids and seizures as well as civil ex parte searches. The United States will continue to monitor Azerbaijan's progress on IPR issues and notes that Azerbaijan will be expected to fully implement the TRIPS Agreement upon accession to the WTO.

### **BAHAMAS**

The Bahamas is being lowered from the Priority Watch List to the Watch List in 2005. During the past year, the Bahamas' legislature passed an amendment to its Copyright Act, which narrows the scope of the compulsory licensing regime for the reception and transmission of copyright works broadcast free over-the-air. The copyright amendment reflects a positive step towards compliance with commitments under an agreement reached between the Bahamas and the United States in 2000. The United States notes its serious concern, however, that this copyright amendment has not yet been enacted or implemented. In addition, the amendment and proposed implementing regulations contain certain deficiencies that we urge the Bahamas to address in the near term. Until this copyright amendment is properly put into effect, problems continue to persist in the area of copyright protection for U.S. cable programs and motion pictures. In particular, in the absence of implementation of the copyright amendments, the compulsory licensing plan contains provisions that allow Bahamian cable operators to retransmit any copyrighted television programming, including for-pay programming, whether or not transmitted from the Bahamas or outside of the Bahamas, and whether or not encrypted. Moreover, until existing regulations are changed, the remuneration system for copyright works under the compulsory licensing program remains inadequate and arbitrarily includes even lower, special rates for hotels and other commercial enterprises. The United States urges the Bahamas to enact promptly these necessary amendments to the copyright law and regulations. In addition, the United States continues to encourage all interested parties, including U.S. cable operators and copyrights holders, to seek commercial solutions that would facilitate the legal transmission of cable programming by cable operators in the Bahamas.

### **BELARUS**

Belarus remains on the Watch List in 2005 because it appears to have not fulfilled its intellectual property commitments under the 1993 U.S.-Belarus Trade Agreement and it continues to have deficiencies in its IPR regime. With respect to its copyright law, Belarus does not provide

appropriate protection for pre-existing works and sound recordings. In addition, it appears that further amendments are needed to bring Belarusian copyright law into compliance with the WIPO Internet Treaties. Enforcement of intellectual property laws in Belarus remains extremely weak and piracy levels remain high. Belarus did not make significant progress during the past year regarding needed legislative reforms or enforcement efforts, although the Government of Belarus is in the process of establishing a national academy to train enforcement officials in IPR protection. In the past, optical media production facilities have migrated into Belarus from neighboring countries, namely the Armita plant in Brest that relocated from Ukraine. The U.S. copyright industry is concerned that unless Belarus takes enforcement actions against illegal optical media plants, additional illegal plants may relocate to Belarus in the future. Belarus has amended its Criminal Code to adopt deterrent penalties for IPR violations, but the Criminal Code still does not provide for ex officio authority to allow police officials to initiate criminal copyright cases or for customs officials to seize illegal products at the border. Furthermore, Belarus' Civil Code does not provide for ex parte searches necessary to protect effectively against end-user software piracy. The United States encourages Belarus to enforce its IPR laws more aggressively and to take actions to deter future illegal operations. In addition, we urge Belarus to fulfill its obligations under the U.S.-Belarus Trade Agreement and will continue to monitor its progress in strengthening its IPR regime.

#### **BELIZE**

We are maintaining Belize on the Watch List in 2005. Although IPR legislation in Belize generally is consistent with international standards, the Government of Belize continued to make only minimal IPR enforcement efforts, which has led to the widespread availability of counterfeit and pirated goods. Furthermore, there has been insufficient cooperation between rights holders and government entities and less than satisfactory responses to concerns raised by such rights holders. A continuing concern is the lack of IPR enforcement in Belize's Corozal Commercial Free Trade Zone, which has led to the proliferation of infringement, transshipment of infringing merchandise, and related criminal activities. We encourage Belize to improve IPR enforcement efforts by increasing the number of investigations of counterfeiting and piracy, prosecuting and sentencing counterfeiters and pirates after successful seizures of illegal goods, and implementing strong IPR enforcement actions in the Corozal Commercial Free Trade Zone.

#### **BOLIVIA**

Bolivia remains on the Watch List in 2005 due to lack of improvements to its IPR regime. Under its bilateral and multilateral commitments, Bolivia should have increased its level of IPR protection years ago. Bolivia's IPR system continues to be deficient with respect to inadequate copyright laws, significant copyright piracy and trademark counterfeiting, and weak IPR enforcement efforts overall. The United States looks to Bolivia to strengthen its copyright law, improve its IPR enforcement mechanisms, and ratify and implement the WIPO Internet Treaties. In addition to these legal reforms, we urge Bolivia to increase its enforcement efforts. Specifically, we recommend that Bolivia provide for civil ex parte searches, prevent unwarranted delays in civil enforcement, provide adequate civil and criminal damages in copyright cases, and strengthen border measures. The U.S. copyright industry reports that Bolivia conducted no raids last year in response to music piracy, which has become so rampant that all international recording companies have closed their offices in Bolivia. Other copyright problems include commercial photocopying of books, unauthorized translations of books, video piracy, and

business and entertainment software piracy. The United States encourages Bolivia to increase its anti-piracy and anti-counterfeiting activities and to institute IPR legislative reforms during 2005.

## **BULGARIA**

Bulgaria is being retained on the Watch List in 2005 due to the dire need for improvements in its IPR regime, particularly with respect to anti-piracy and anti-counterfeiting enforcement efforts. Copyright piracy has increased in the past few years, after a period of dramatic decline in the mid- to late-1990's. The Bulgarian Government has not taken effective steps to stop the increase in piracy and counterfeiting activity. The U.S. copyright industry reports that this past year Bulgaria had high rates of optical disc piracy, estimating that approximately 70 percent of all foreign sound recordings produced in Bulgaria were illegal copies. Pirated CDs and DVDs are increasingly available throughout the country. We are encouraged by recent reports that the Bulgarian Government is taking steps to implement a new optical media licensing system, including current efforts by Bulgaria's Parliament to pass its optical disc legislation. However, the U.S. copyright industry reports that the proposed optical disc legislation needs to be amended in certain respects prior to its adoption. We will continue to closely watch these legislative developments in Bulgaria. In addition, we recommend that Bulgaria amend its criminal code and criminal procedure code to correct severe shortcomings which undercut the possibility of effective enforcement. For example, we hope that Bulgaria will improve its polycarbonate import registration scheme, an important tool for addressing optical disc piracy. With respect to IPR enforcement, Bulgarian police authorities have increased their cooperation with rights holders. However, despite some progress in the area of enforcement, enforcement of the current optical disc licensing regime is ineffective. Judicial trials are replete with extensive delays and convicted pirates and counterfeiters usually receive only minimal sentences. There are currently eight known operational optical disc plants in Bulgaria, with the output of those plants far exceeding the country's legitimate demand. In addition, production and smuggling of counterfeit distilled spirits has continued to grow. While Bulgaria has increased its investigations into the sources of counterfeit production and distribution, no criminal charges have been filed as a result of these inquiries. We remain concerned with the increases in copyright piracy and trademark counterfeiting, and the United States will continue to monitor Bulgaria's near-term progress in combating these illegal activities.

## **CANADA**

Canada is being maintained on the Special 301 Watch List in 2005, and the United States will conduct an out-of-cycle review to monitor Canada's progress on IPR issues during the upcoming year. We urge Canada to ratify and implement the WIPO Internet Treaties as soon as possible, and to reform its copyright law so that it provides adequate and effective protection of copyrighted works in the digital environment. The Canadian court decision finding that making files available for copying on a peer-to-peer file sharing service cannot give rise to liability for infringement under existing Canadian copyright law underscores the need for Canada to join nearly all other developed countries in implementing the WIPO Internet Treaties. The U.S. copyright industry is concerned about proposed copyright legislation regarding technological protection measures and internet service provider (ISP) liability, which if passed, would appear to be a departure from the requirements of the WIPO Internet Treaties as well as the international standards adopted by most OECD countries in the world. The United States urges Canada to adopt legislation that is consistent with the WIPO Internet Treaties and is in line with the

international standards of most developed countries. Specifically, we encourage Canada to join the strong international consensus by adopting copyright legislation that provides comprehensive protection to copyrighted works in the digital environment, by outlawing trafficking in devices to circumvent technological protection measures, and by establishing a “notice-and-takedown” system to encourage cooperation by ISPs in combating online infringements. It also is imperative that Canada improve its enforcement system so that it can stop the extensive trade in counterfeit and pirated products, as well as curb the amount of transshipped and transiting goods in Canada. The United States also urges Canada to enact legislation that would provide a stronger border enforcement system by giving its customs officers greater authority to seize products suspected of being pirated or counterfeit. We also encourage greater cooperation between Customs and the Royal Canadian Mounted Police in enforcement matters, and encourage Canada to provide additional resources and training to its customs officers and domestic law enforcement personnel. Canada's border measures continue to be a serious concern for IP owners. With respect to data protection, we recognize that Canada has taken positive steps to improve its data protection regime. The U.S. pharmaceutical industry is concerned about certain aspects of the proposed regulations. The United States will use the out-of-cycle review to monitor Canada's progress in providing an adequate and effective IPR protection regime that is consistent with its international obligations and advanced level of economic development, including improved border enforcement and full implementation of data protection.

## **CHILE**

Chile will remain on the Watch List in 2005. We note Chile's efforts to bring its IPR regime into compliance with the TRIPS Agreement and the U.S.-Chile Free Trade Agreement (FTA). Chile's Congress approved in December 2003 legislation intended to bring the country into compliance with a number of TRIPS commitments. Chile still needs significant reforms, however, in a number of areas. Copyright and trademark enforcement must be improved, including the imposition of deterrent penalties. Copyright piracy is still a serious problem in Chile, and the U.S. copyright industry indicates that digital piracy has contributed to a dramatic rise in piracy in Chile. Concerns remain over pending additional copyright legislation introduced in 2004 which, while making some improvements in enforcement mechanisms, appears to fall short of providing deterrent penalties. Regarding protection for pharmaceutical products, we are concerned that Chile has yet to implement effective regimes to protect test data against unfair commercial use, as well as provide coordination between its health authorities and patent office to prevent marketing registrations of patent-infringing products. We hope that these issues will be resolved through Chile's full implementation of the FTA and we will monitor Chile's progress in meeting its commitments.

## **COLOMBIA**

Despite Colombia's progress in certain areas toward strengthening its IPR regime, Colombia still needs to make further improvements and therefore will remain on the Watch List for 2005. Colombia is the only Andean country to provide a full five years of data protection for pharmaceuticals. In the copyright context, Colombia has increased criminal penalties for copyright infringement and has established a specialized IPR unit in the Prosecutor General's office. Notwithstanding these improvements, however, high levels of piracy continue to dominate the Colombian market. The U.S. copyright industry estimates its losses in 2004 due to music piracy alone at \$51 million in Colombia, and reports that 71 percent of the music sold in

Colombia is pirated product; the U.S. copyright industry estimates losses across all copyright sectors at \$131 million last year. Other areas of copyright piracy are on the rise, including optical disc piracy (both CD-Rs and DVD-Rs), illegal photocopying of academic textbooks, business software piracy, and entertainment software piracy. These high piracy levels plus a lack of successful prosecutions for IPR infringement remain problematic. Efforts to combat piracy through raids and other enforcement measures are hindered by a judicial system that fails to actively prosecute cases or issue deterrent criminal sentences. Border enforcement is weak, administrative enforcement against signal theft piracy needs improvement, and it can take as long as six months to carry out inspections after requesting civil ex parte search orders. The United States urges Colombia to ensure that its criminal, administrative, civil and border enforcement procedures meet its longstanding bilateral and multilateral intellectual property enforcement obligations and are implemented effectively in the near future.

### **COSTA RICA**

In August 2004, Costa Rica signed the United States-Dominican Republic-Central American Free Trade Agreement (CAFTA-DR). The United States commends Costa Rica's commitment to ensuring that its IPR legislation conforms to the TRIPS Agreement and CAFTA-DR. However, Costa Rica still faces significant IPR enforcement problems that warrant keeping Costa Rica on the Watch List in 2005. We urge the Government of Costa Rica to modify its data protection law to provide the requisite level of protection, as well as amend its patent law to meet international standards and Costa Rica's international and CAFTA-DR obligations. We urge the Government of Costa Rica to not adopt proposed legislation that would weaken the criminal procedure code for IPR enforcement, but recommend that companion legislation which continues strong criminal sanctions be considered instead. We encourage the Government of Costa Rica to take immediate action in 2005 to improve the shortcomings in its IPR enforcement system by assigning priority and resources to enforcement efforts against piracy and counterfeiting. In light of CAFTA-DR, we also urge the Government of Costa Rica to ensure that its local IPR legislation conforms fully to its CAFTA-DR obligations.

### **CROATIA**

Croatia will remain on the Watch List in 2005 due to limited progress on IPR issues. Although Croatia passed an amendment to its drug registration law in December 2004 that provided protection for test and other data from unfair commercial use, Croatia still fails to provide coordination between its national patent authority and its central health regulatory authority to prevent marketing registrations for patent-infringing products. As a result, the U.S. pharmaceutical industry reports that companies are easily able to register patent-infringing pharmaceuticals in Croatia. We will continue to monitor Croatia's progress on this issue in 2005.

### **DOMINICAN REPUBLIC**

IPR protection has not improved significantly in the Dominican Republic during the past year, and thus it will remain on the Watch List in 2005. The Dominican Republic signed the U.S.-Dominican Republic-Central America Free Trade Agreement (CAFTA-DR) with the United States in August 2004 that will require the Dominican Republic to upgrade considerably its IPR protections. Concerns still remain regarding the protection and enforcement of intellectual property, particularly with respect to ongoing broadcast piracy and ineffective prosecution of

copyright and trademark infringement cases. We encourage the Dominican Republic to improve its enforcement regime to solve the broadcast piracy problem and deter other copyright infringements more effectively in the near future, as well as to focus its efforts on ensuring an expeditious resolution of pending criminal cases. Finally, we urge the Dominican Republic to be vigilant in submitting legislation, enhancing IPR enforcement, providing training, and making other necessary preparations to meet its FTA obligations. The United States will continue to work with the Dominican Republic to strengthen its IPR regime, particularly in the context of CAFTA-DR.

## **ECUADOR**

Ecuador has made minimal progress in improving its IPR regime over the last year, and it will remain on the Watch List in 2005. Although Ecuador generally has an adequate IPR law, enforcement of the law remains a central problem. Enforcement of copyrights is a significant problem, especially with respect to sound recordings, computer software, and illegal commercial photocopying of books. The U.S. copyright industry reports high piracy levels due to insufficient IPR enforcement by Ecuador, including poor border controls, infrequent ex officio raids, and limited government resources dedicated to anti-piracy and anti-counterfeiting activities. Music piracy has become so severe that the majority of international record companies have closed their offices in Ecuador. Even though Ecuador's current substantive copyright legislation has been modernized in line with its international obligations, Ecuador's judicial system remains deficient because the courts appear unwilling to enforce the law. The Ecuadorian Government has not yet established the specialized intellectual property courts required by its IPR law. Petitions for civil ex parte actions are brought before civil courts, delaying or preventing seizure orders for pirated or counterfeit products. Concerns also remain over Ecuador's current lack of effective protection for undisclosed test data submitted for marketing approval of pharmaceutical and agricultural chemical products. The United States urges Ecuador to strengthen enforcement of IPR and will closely monitor Ecuador's efforts to address IPR-related concerns.

## **EUROPEAN UNION**

For several years, including in 2004, the EU was on the Priority Watch List primarily because of its lack of willingness to address deficiencies in EU Regulation 2081/92 ("EU GI Regulation"), which governs the protection of geographical indications (GIs) for agricultural products and foodstuffs in the EU, as well as lack of full implementation of the EU Biotech Directive by EU member states. In 1999, the United States initiated dispute settlement consultations with the EU, on the grounds that the EU GI Regulation was inconsistent with the EU's obligations under TRIPS. After consultations failed to resolve the dispute, it was referred to a WTO dispute settlement panel in 2003. The resulting panel report, finding in favor of the United States that the EU GI Regulation impermissibly discriminates against U.S. products and producers, was adopted by the WTO dispute settlement body on April 20, 2005. The United States expects that the EU will now implement the recommendations and rulings of the dispute settlement panel, consistent with WTO rules. We are lowering the EU from the Priority Watch List to the Watch List in 2005, with the expectation that the EU will now implement these recommendations and rulings. However, the United States plans to initiate an out-of-cycle review to monitor developments in connection with the EU's application of the EU GI Regulation and the EU's implementation of the WTO dispute settlement panel's recommendation and rulings. In



addition, lack of full implementation of the EU Biotech Directive (98/44/EC) by EU member States continues to be a concern. We look forward to continued cooperation between the United States and the EU on intellectual property matters.

### **GUATEMALA**

Guatemala remains on the Watch List in 2005 due to continuing concerns with its IPR regime. The principle IPR concerns currently facing Guatemala include high levels of piracy and counterfeiting. Guatemala signed the U.S.-Dominican Republic-Central America Free Trade Agreement (CAFTA-DR) with the United States that will require Guatemala to upgrade considerably its IPR protections. The United States commends Guatemala's commitment to ensuring that its IPR legislation conforms to the TRIPS Agreement and CAFTA-DR, including its recent reinstatement of protection of proprietary data against unfair commercial use for pharmaceutical and agricultural chemical products.

### **HUNGARY**

Hungary has made improvements to its IPR regime in the past several years, but still needs additional improvement in certain areas. Thus, Hungary will be maintained on the Watch List in 2005 to monitor its progress. The key issues facing the U.S. copyright industry include prosecutorial delays, low fines or weak sentences, and weak border enforcement. We commend Hungary for modernizing its copyright code, but urge Hungary to enforce these laws in order to curb piracy within its borders. Problems exist with piracy of sound recordings (CDs and CD-Rs) and motion pictures (DVD-Rs), unauthorized optical disc plants, channels of marketing and distribution of pirated discs through the Internet, business and entertainment software piracy, and unauthorized photocopying of books. In the pharmaceutical context, Hungary does not provide any coordination between its health regulatory agency and its patent authority to prevent the marketing registrations of patent-infringing products. We urge the Hungarian Government to address these issues and to continue to improve IPR enforcement efforts in all intellectual property areas.

### **ITALY**

Despite Italy's continued implementation of the 2000 Copyright Law and its subsequent amendments, increased enforcement actions in 2004 and decreased piracy rates for selected products, Italy continues to possess one of the highest overall piracy rates in Western Europe. Counterfeiting remains a concern as well. For these reasons, Italy will remain on the Watch List for 2005. The United States has reached out to Italy to express our concern over its IPR regime, but we have not seen sufficient improvements to warrant removal from the Watch List.

Widespread piracy exists, primarily due to chronic problems with the piracy of business and entertainment software, piracy of video forms of motion pictures, music piracy, and widespread book piracy. Implementation of Italy's Copyright Law amendments is resulting in more active enforcement efforts and more frequent imposition of deterrent penalties by the Italian judiciary. However, the U.S. copyright industry is concerned that Italy may be amending its anti-piracy legislation in a manner that will undermine ongoing IPR enforcement efforts. In most sectors, the U.S. copyright industry reports that the number of raids, product seizures, and arrests rose in 2004. We continue to observe wide variations in the effectiveness of IPR enforcement activities within Italy. The United States will continue to work with Italy to raise awareness regarding intellectual property issues and to improve IPR protection across all sectors.

## **JAMAICA**

Jamaica remains on the Watch List in 2005. Jamaica's trademark and copyright laws are generally in line with international standards, although we remain concerned over continued problems with Jamaica's delay in enacting the Patents and Designs Act to meet its obligations under the TRIPS Agreement and the U.S.-Jamaica bilateral IP Agreement. We urge the Government of Jamaica to reform its patent law as soon as possible to comply fully with international standards for patent protection.

## **KAZAKHSTAN**

Kazakhstan remains on the Watch List in 2005 so we can monitor further progress on IPR protection and enforcement. Although Kazakhstan has fulfilled a number of its IPR obligations under the 1992 U.S.-Kazakhstan Trade Agreement, some additional steps are required. In particular, Kazakhstan needs to toughen penalties and further empower law enforcement officers to pursue IPR cases. Kazakhstan ratified the WIPO Internet Treaties in 2004 and amended its Copyright Law to provide protection for pre-existing works and sound recordings. In October 2004, the Kazakh Government submitted to Parliament amendments to the Criminal Code that would lower the monetary threshold for commencement of a criminal IPR prosecution and would provide law enforcement agencies with ex officio authority to seize suspected infringing material. Kazakhstan's Civil Procedure Law still does not appear, however, to provide for civil ex parte search procedures needed to provide enforcement against end-user software pirates. In addition, there are few convictions, and those who are convicted receive only minimal penalties. As a result, piracy is still a major problem. We urge the Government of Kazakhstan to continue strengthening its IPR provisions and creating a tighter enforcement regime.

## **KOREA**

Over the past year, Korea has taken significant steps to strengthen its intellectual property regime. We are lowering Korea from the Priority Watch List in 2004 to the Watch List this year to recognize Korea's efforts. Meaningful improvements made by Korea include: introducing legislation that will create protection for sound recordings transmitted over the Internet (using both peer-to-peer and web casting services); implementing regulations that restore the ability of the Korea Media Rating Board to take necessary steps to stop film piracy; and increasing enforcement activities by the Standing Inspection Team against institutions using illegal software. Notwithstanding these improvements, more needs to be done to further update Korea's intellectual property regime to keep pace with the digitization of Korea's economy, and to prevent the proliferation of unauthorized copying of copyrighted material. In particular, we look to Korea to join other economically advanced countries by extending the exclusive reproduction right to cover temporary copies, such as those made in the temporary memory of a computer -- an enormous and still growing manner of using copyrighted works. In addition, we call on Korea to further strengthen the relevant provisions of its Copyright Act and Computer Programs Protection Act related to technological protection measures and ISP liability, to clarify the scope of the private copy exception, and to join the global trend to extend the term of copyright protection for works and sound recordings. The United States has urged Korea to continue accelerating efforts to combat piracy of DVDs, computer software, and university textbooks, as well as to decrease street vendor sales of pirated and counterfeit goods. The United States also has emphasized the importance of Korea continuing to fulfill its WTO TRIPS obligations in the

near term to provide adequate protection of pharmaceutical test data from unfair commercial use. We encourage Korea to improve coordination between the Korean health and patent authorities to prevent marketing authorizations of patent-infringing products. We welcome the progress that Korea has made, will closely monitor to ensure that the pending copyright legislation is implemented with appropriate safeguards to prevent the erosion of these or other rights, and look forward to future improvements to Korea's IPR regime.

## **LATVIA**

Latvia made improvements to its IPR legislative framework in 2004, but needs to follow through with its commitments to strengthen IPR enforcement. Latvia will be maintained on the Watch List in 2005 to monitor its enforcement activities. Latvia continues to be a significant consumer of and transshipment market for pirated goods, especially from Russia. Piracy levels for motion pictures, records, music, and entertainment software remain high, and Internet piracy is growing in the areas of music hosting, entertainment software, and pirated video games. The lack of effective border enforcement continues to be a key problem in Latvia. Customs officials are not taking sufficient action to inspect or seize shipments of pirated audio CDs, CD-ROMS containing business software, videos, and audio cassettes coming into Latvia from Lithuania, Russia and elsewhere. Such goods are then transshipped to the rest of the European Union. We recommend that Latvia coordinate with neighboring customs officials, provide training for Latvian customs officials, and increase its commitment of resources to address the enforcement problem effectively. Latvia improved its IPR protection during the past year, passing Latvian Copyright Law amendments that implemented the WIPO Internet Treaties. Substantive problems remain, however, such as the lack of civil ex parte searches. The United States encourages Latvia to demonstrate its commitment to IPR enforcement by strengthening and investing adequate resources in its customs border enforcement activities.

## **LITHUANIA**

Despite Lithuania's progress in improving its legal framework for protecting IPR and fighting software piracy, we are maintaining Lithuania on the Watch List in 2005 to monitor some key issues. Optical media piracy levels remain high in Lithuania, which is a central transshipment point in the Baltic region for mostly Russian-produced optical media to the rest of Europe. The lack of IPR enforcement by customs officials remains troubling, along with the lack of deterrent sentences imposed by courts. The U.S. copyright industry reports significant copyright problems in the areas of border enforcement, optical media piracy, and Internet piracy (particularly with the sale of pre-recorded CDs and CD-Rs over the Internet). High rates of piracy also are reported in the sectors of music (pirated CDs and CD-Rs), entertainment and business software, and motion pictures (pirate videocassettes, home-burned optical discs, and television and local cable piracy). While we commend Lithuania for its IPR legislative progress, we note that some deficiencies remain in its copyright law. The United States also urges Lithuania to implement optical media rules that regulate the production, distribution, and export of optical media effectively. In addition, we urge Lithuania to implement its regulation on government use of legitimate software. The United States also encourages Lithuania to direct its attention and resources to increasing its anti-piracy and anti-counterfeiting efforts by coordinating among relevant government ministries, police, and customs officials.

## **MALAYSIA**

Malaysia is publicly committed to strong IPR protection and enforcement, but nonetheless has high piracy rates for optical media and is a substantial exporter of counterfeit and pirated products. Malaysia also does not protect pharmaceutical and agricultural chemical test data from unfair commercial use. For these reasons, the United States will keep Malaysia on the Watch List in 2005 to monitor additional progress on improving its IPR regime. The Government of Malaysia increased its enforcement efforts during the past year, including: conducting raids against pirate optical disc production facilities, retail stores, copy shops, and companies suspected of using illegal software; seizing pirate goods; and ensuring that judicial proceedings meted out some severe criminal penalties. However, despite these improvements, the U.S. copyright industry reports that Malaysia has become the most significant producer/exporter of pirated optical disc entertainment software in the world. The U.S. copyright industry estimated its losses in Malaysia at approximately \$188 million in 2004. The United States urges Malaysia to continue its enforcement efforts and to focus on the closing of licensed and unlicensed optical disc plants that are producing pirated products, and stopping the export of such pirated goods. In addition, the United States notes that Malaysia should address several deficiencies in its Copyright Law, particularly with respect to allowing copyright owners to enforce their rights in civil or criminal cases. Trademark counterfeiting is rampant in Malaysia due to poor enforcement, including in regard to optical media, apparel and luxury goods, tobacco, mobile phone batteries, and toys. According to the U.S. pharmaceutical industry, drug counterfeiting is a growing problem in Malaysia, but we are concerned about Malaysia's new "solution" that requires pharmaceuticals to carry a mandatory hologram security sticker to curb counterfeits. The stickers themselves are vulnerable to copying and may in fact make it easier for counterfeiters to pass pirated product as genuine. Malaysia has enacted neither protection for confidential test data nor a coordination mechanism between the health authorities and patent office to prevent unauthorized registrations of patent-infringing products. The United States will work with Malaysia to make progress on these pressing IPR issues through the Trade and Investment Framework Agreement (TIFA) discussions, and we hope to see continued progress from the Government of Malaysia in the near future.

## **MEXICO**

Mexico will be retained on the Watch List in 2005 due to increasing copyright piracy and trademark counterfeiting rates. Despite an increase in the number of searches and seizures of counterfeit and pirated goods, the scope of IPR violations continues to outpace the Government of Mexico's IPR enforcement efforts, with U.S. copyright industry loss estimates increasing in 2004 to \$870 million. Pirated sound recordings and motion pictures are widely available throughout Mexico, crippling legitimate copyright-related businesses. As noted in last year's Special 301 Report, concerns remain over the 2003 amendments to Mexico's copyright law, which failed to address the comprehensive reforms needed by Mexico to implement effectively the obligations of the WIPO Internet Treaties and to erase doubts concerning inconsistencies in Mexico's copyright law with its obligations under NAFTA and the TRIPS Agreement; regulations to implement these amendments still have not been issued. The United States urges Mexico to expand its public education campaigns and take the necessary steps to resolve the current legislative copyright deficiencies. Enforcement in Mexico remains weak, and raids by Mexican authorities infrequently result in convictions of or deterrent penalties against pirates or counterfeiters. To strengthen enforcement, the United States urges Mexico to expand anti-piracy and anti-counterfeiting efforts against commercial distribution, street piracy and counterfeiting;

impose strong criminal penalties and destroy seized products; and increase the speed of administrative and judicial actions. Companies continue to report widespread counterfeiting of trademarked products. Despite continuing to raise long-standing concerns over these issues, many trademarks owners in Mexico still have problems with enforcement and case administration. When counterfeit items are discovered, injunctive relief measures issued against trademark infringers are often unenforceable. The United States commends Mexico for its effort to provide protections for patents and confidential test data, but the U.S. pharmaceutical industry reports that the Ministry of Health has provided marketing registrations for unauthorized copies of patent-infringing pharmaceutical products. The United States will work with Mexico to address and resolve these IPR concerns in an effective manner.

## **PERU**

Peru will be kept on the Watch List in 2005. Both the United States Government and U.S. industry remain concerned with Peru's current lack of protection for undisclosed test data submitted for marketing approval of pharmaceutical and agricultural chemical products. Peru also does not provide second use patents, and no coordination mechanism exists between its health authorities and patent office to prevent registrations of unauthorized patent-infringing products. Regarding copyright protection, the Peruvian Government took some steps toward improving enforcement through its "Anti-Piracy Crusade" initiated in 2002; however, piracy remains high for sound recordings, business and entertainment software, books, and motion pictures. According to the U.S. copyright industry, piracy of sound recordings has been on the increase in the last several years and is so severe now (98% of the market was estimated to be pirated goods in 2004) that it has virtually eliminated any legitimate market and caused the remaining legitimate sound recording businesses to shut down. Optical media piracy is on the rise in all sectors, particularly with respect to the audiovisual industry due to a tremendous growth in pirate optical discs. The Government of Peru, in coordination with the private sector, has conducted numerous raids over the last few years on large-scale distributors and users of pirated goods and has increased enforcement activities. However, piracy and weak IPR border enforcement measures continue to be significant problems for copyright owners. The United States urges Peru to strengthen IPR protection and enforcement and will continue to monitor Peru's efforts in addressing these concerns.

## **POLAND**

Poland will remain on the Watch List in 2005 in order to monitor its progress in improving IPR protection. The United States conducted an out-of-cycle review for Poland in late 2004 to evaluate whether Poland was continuing its efforts to strengthen anti-piracy and anti-counterfeiting measures at the Warsaw Stadium and continue effective raids and prosecutions against piracy and counterfeiting activities across the country, strengthen border enforcement, adopt and implement copyright law amendments and optical disc regulations, and take concrete, effective steps to strengthen domestic enforcement of IPR. Poland demonstrated some progress on most elements of IPR protection that were outlined in last year's Special 301 Report, but deficiencies remain in patent protection for pharmaceuticals, especially the lack of coordination between the Health Ministry and the Polish patent agency that would prevent the registration of unauthorized patent-infringing products. The Polish Parliament passed copyright legislation and optical disc licensing regulations this year. Poland has increased anti-piracy efforts, improved enforcement of most (but not all) copyright products at the Warsaw Stadium, and has closed two

illegal CD production facilities that were supplying the Warsaw Stadium. The Ministry of Culture has instituted new reporting and inspection requirements concerning optical disc production and the equipment used to produce optical disc media. Despite these notable improvements in Poland, a significant volume of pirated optical media products (CDs, DVDs, and CD-ROMS), including illegal sound recordings, audiovisual products, videogames, and business software applications, continue to enter Poland. Large amounts of pirated music imports enter Poland from Ukraine, Lithuania, Belarus, and Russia, while pirate movie DVDs enter from Russia, and pirate software enters from Russia, Ukraine, Malaysia, and China. Significant amounts of pirate cartridge-based videogames arrive in Poland from the Greater China region. In addition, Internet piracy, including piracy at Internet cafés, presents a growing problem in Poland. The United States commends Poland for its heightened efforts over the past year to improve its IPR regime, and we encourage Poland to continue this progress by committing its resources and attention to IPR enforcement and issues related to pharmaceuticals as outlined above.

### **ROMANIA**

Romania will remain on the Watch List in 2005, and we will continue monitoring several IPR enforcement-related issues. Although Romania improved its IPR regime in 2004 by amending its Copyright Law to include civil ex parte search authority, IPR enforcement did not improve in Romania in 2004. The U.S. copyright industry continued to experience high piracy rates and significant losses in Romania in 2004 due to weak enforcement and judicial deficiencies. The U.S. copyright industry remains frustrated with an apparent lack of appreciation for the importance of IPR protection and the significant social and economic effects that piracy has on industry. While domestic IPR laws provide for adequate substantive protection, enforcement efforts remain weak and ineffective. It appears that law enforcement agencies and the judiciary place a low priority on IPR enforcement. For example, the Romanian judiciary has dismissed a large number of cases on the grounds that there is a “lack of social harm.” The United States urges Romania to improve and adequately fund its enforcement activities in order to combat piracy. In 2004, Romania implemented data protection legislation. Romania recently stated its intention to strengthen its IPR laws to reflect international standards. The United States encourages this approach and looks forward to seeing further improvements in Romania’s IPR regime.

### **SAUDI ARABIA**

The United States commends Saudi Arabia for improving its legal protections in laws to protect intellectual property as part of its ongoing efforts to join the WTO, where Saudi Arabia will be required to comply fully with the TRIPS Agreement upon the date of accession to the WTO. Saudi Arabia will remain on the Watch List in 2005, and the United States will conduct an out-of-cycle review to monitor Saudi Arabia’s progress on IPR issues during the coming year. Saudi Arabia still needs to resolve a number of IPR issues. For example, Saudi Arabia’s newly amended copyright law offers greater protection for IPR through strengthened penalties, but still lacks some basic minimum standards that are required by the WIPO Internet Treaties and TRIPS, including providing for destruction of seized goods, materials, and machinery, and failure to provide for recovery of litigation costs. Implementing regulations also need to be finalized for the copyright law. The United States urges Saudi Arabia to continue improving its enforcement efforts, and commends Saudi Arabia for its recent accomplishment of conducting a large-scale

raid in Riyadh in March 2005 that led to the seizure of 1.2 million audio-visual materials and the arrests of more than 250 individuals. Despite improvements made by Saudi Arabia on IPR legislation, the U.S. copyright industry reports that piracy rates remain high due to the absence of deterrent penalties and the lack of transparency in Saudi Arabia's enforcement system. We urge Saudi Arabia to improve its enforcement efforts by continuing to conduct raids, introducing a robust customs enforcement program, allow rights holders to send experts to cooperate with customs authorities, provide reports to rights holders, impose deterrent sentences, continue to enforce the software usage directive, continue sustained raids to prevent unauthorized redistribution of pay television services, and work with universities to use legal textbooks and stop illegal copying of books. With respect to the pharmaceutical industry, Saudi Arabia has protected IPR related to pharmaceutical products, and there have not been major incidences of patent infringement. We note, however, that Saudi Arabia has a continued backlog of pending patent applications, which it intends to clear by the end of 2006. The United States will continue to work with Saudi Arabia on these IPR issues through the Trade and Investment Agreement (TIFA) and WTO accession process, as well as the out-of-cycle review.

### **SLOVAKIA**

Slovakia remains on the Watch List in 2005 to monitor progress on IPR issues. The situation has not improved over the past year, although Slovakia has expressed its interest in taking steps to address inadequacies in its IPR regime. Slovakia currently does not provide a coordination mechanism between its health regulatory agency and its patent authority to prevent the registration of unauthorized patent-infringing products, and the U.S. pharmaceutical industry reports that Slovakia continues to store sensitive registration data on the premises of a generic drug manufacturer. We urge Slovakia to provide coordination between its health and patent authorities and to resolve these related issues.

### **TAIWAN**

The United States lowered Taiwan at the end of 2004 from the Priority Watch List (where it had been since 2001) to the Watch List as part of the out-of-cycle review, in recognition of Taiwan's successful passage of strengthened copyright legislation and improved IPR enforcement. However, Taiwan will remain on the Watch List in 2005 as we continue to monitor Taiwan's efforts to combat Internet piracy, enact judicial reforms, implement the new data protection law, prevent illegal copying of textbooks, abolish the Export Monitoring System (EMS), and prevent unauthorized cable operations in South and Central Taiwan. In August 2004, Taiwan's legislature approved a number of amendments to its copyright law that provide greater protection for copyrighted works and increase penalties for infringers. In addition, Taiwan authorities made permanent an IPR-specific task force that has increased the frequency and effectiveness of raids against manufacturers, distributors, and sellers of pirated product. In January 2005, Taiwan's legislature amended its pharmaceutical law to provide a five-year term of protection for pharmaceutical test data. Implementing regulations are currently being drafted in consultation with rights holders and the law is scheduled to go into effect by July 2005. With respect to the judicial process, Taiwan authorities continue to conduct regular training seminars for judges and prosecutors on IPR matters and plan to establish a specialized IPR court. During the past year, Taiwan's IPR task force increased inspections of optical media factories and retail distribution centers, and the number of raids and inspections conducted by the National Police also increased sharply. The U.S. copyright industry reports that Taiwan's increased enforcement efforts

resulted in a significant drop in estimated trade losses from a high of \$847.9 million in 2002 to \$315.5 million in 2004. The United States commends Taiwan for its accomplishments on these important issues. However, we continue to look to Taiwan to improve its efforts in such areas as effectively combating increasing levels of Internet piracy of copyrighted works, further reducing corporate end-user business software piracy, and halting the illegal copying of textbooks. Other issues that require monitoring include transshipment of counterfeit and pirated goods to third areas, ensuring that changes to Taiwan's export monitoring system do not result in a resurgence of counterfeit exports, effectively halting the spread of counterfeit pharmaceuticals, and stopping unauthorized cable operations in central and southern Taiwan. We urge Taiwan to continue making progress by addressing these remaining IPR concerns, and we will work together with Taiwan to achieve further progress.

### **TAJIKISTAN**

The United States is concerned that Tajikistan still needs to fulfill its IPR obligations under the 1993 bilateral agreement. Tajikistan, therefore, will remain on the Watch List in 2005, where it has been since 2000. Specifically, Tajikistan is not yet a member of the Geneva Phonograms Convention, and Tajikistan's Copyright Law does not clearly provide protection for pre-existing works or sound recordings. In addition, Tajikistan has a weak enforcement regime, since it does not provide criminal penalties for IPR violations, does not provide ex officio authority to commence criminal cases, and does not provide for civil ex parte search procedures necessary to provide effective enforcement against end-user pirates. The Tajik Customs Code also fails to provide customs officials with ex officio authority to suspend the release of suspected infringing materials at the border. The United States urges Tajikistan to address deficiencies in its IPR laws and strengthen IPR protection and enforcement.

### **THAILAND**

Thailand has made some efforts to strengthen its IPR regime during 2004. We are keeping Thailand on the Watch List in 2005 to monitor further progress. The Thai authorities conducted a number of inspections and raids in July 2004, and in late 2004 they cooperated with rights holders to conduct an enforcement campaign called "Operation Eradicate," which raided dozens of factories and warehouses, yielded seizures of millions of pirated discs, and decommissioned several replication machines used for copyright infringement. We note Thailand's efforts, and encourage Thailand to continue with activities such as this on a frequent and sustained basis to achieve a decrease in piracy and counterfeiting and strengthening of its IPR system. The U.S. Government and U.S. copyright industry remain concerned, however, over the growing problem of optical disc piracy at plants in Thailand, as well as deficiencies in Thailand's optical disc legislation. Piracy also remains high in the areas of photocopying of books, cable piracy, videogame piracy, business software end-user piracy, Internet piracy of music, and unauthorized public performances of motion pictures and television programs in hotels, bars, and restaurants. The United States urges Thailand to establish an effective system to license and regulate broadcast and cablecasting facilities, including having the authority to take actions that will deter illegal broadcasters. The production, distribution, sale, and export or transshipment of pirate and counterfeit products continues to be a serious concern to the U.S. copyright and trademark industries. The U.S. pharmaceutical industry also is concerned about Thailand's failure to date to enact implementing regulations for the Trade Secrets Act to provide effective data protection in line with Thailand's existing international commitments. Additional concerns include delays



in pharmaceutical patent approvals from the Thai Department of Intellectual Property, lack of coordination between the Thai health authorities and patent authorities, and the proliferation of manufacturing, packaging, and distribution of counterfeit drugs. The United States will continue to work with Thailand to address our significant concerns regarding its intellectual property laws and enforcement, and to urge the Thai Government to take swift action to implement specific elements of the IPR Action Plan. The Thai Government's prompt and full implementation of the IPR Action Plan will provide an essential foundation for the successful conclusion of the U.S.-Thailand Free Trade Agreement between our two governments.

### **TURKMENISTAN**

Turkmenistan has been on the Watch List since 2000, and it will remain on the Watch List in 2005 due to its lack of progress on IPR issues during the past year. Turkmenistan has numerous remaining steps to take in order to fulfill its IPR obligations under the 1993 U.S.-Turkmenistan Trade Agreement. Specifically, Turkmenistan is a member of neither the Berne Convention nor the Geneva Phonograms Convention, and it has not yet signed the WIPO Internet Treaties. Turkmenistan has not modernized its Copyright Law and consequently does not provide any protection to foreign sound recordings. IPR enforcement is inadequate, since Turkmenistan has not adopted criminal penalties for IPR violations, and the Turkmen Customs Code does not provide ex officio authority to seize suspected infringing material at the border. There are no known civil ex parte search procedures. The United States urges Turkmenistan to adopt the legal reforms that will bring Turkmenistan into compliance with its obligations under the bilateral 1993 U.S.-Turkmenistan Agreement, and to undertake enforcement activities that will help strengthen its IPR regime.

### **URUGUAY**

The Government of Uruguay has made some IPR improvements during 2004, and we are keeping Uruguay on the Watch List to monitor further IPR progress. We commend Uruguay for approving in 2004 the implementing regulations for its new copyright legislation, which have been largely put into effect and appear to be contributing to the strengthening of Uruguay's copyright regime. Despite this progress, however, we note that Uruguay has not yet ratified the WIPO Internet Treaties. Piracy of copyrighted works still proliferates and IPR enforcement remains ineffective. Uruguay also fails to provide adequate protect confidential test data from unfair commercial use as required by TRIPS. We urge the Uruguayan Government to ratify the WIPO Internet Treaties, address its deficiencies in IPR enforcement against piracy and counterfeiting, and provide protection for confidential test data.

### **UZBEKISTAN**

Uzbekistan is currently contemplating amendments to several IPR-related laws, and the United States is keeping Uzbekistan on the Watch List in 2005 with the hope that additional progress will be made on IPR protection and enforcement in the near future. While Uzbekistan recently joined the Berne Convention, the United States notes with concern Uzbekistan's reservation to Article 18, which provides protection for pre-existing works. Furthermore, Uzbekistan appears to be out of compliance with its intellectual property commitments under the 1994 U.S.-Uzbekistan Trade Agreement, particularly with respect to copyright protection and enforcement. Uzbekistan does not provide protection for sound recordings or pre-existing works, and is not a member of the Geneva Phonograms Convention or the WIPO Internet Treaties. In addition, IPR

enforcement in Uzbekistan remains very weak due to a lack of ex officio authority that would allow customs officials to seize infringing materials at the border, a lack of civil ex parte search procedures, and inadequate criminal penalties for IPR violations. The United States urges Uzbekistan to remedy these deficiencies in its IPR laws and to take immediate and effective measures to improve enforcement.

## **VIETNAM**

Vietnam will remain on the Watch List in 2005 to encourage further progress on IPR issues, especially continued implementation of the intellectual property provisions of the U.S.-Vietnam Bilateral Trade Agreement (BTA). The United States and Vietnam have been working together to address IPR issues during WTO accession discussions, and we hope to see continued progress this year. Vietnam is obligated to provide high standards of IPR protection pursuant to the U.S.-Vietnam BTA. Vietnam has amended some of its IPR legislation this year, although a considerable amount of work is still necessary in the legislative arena, particularly with respect to copyright, data protection, and patents. IPR infringement remains rampant in Vietnam, and enforcement continues to be ineffective despite some improvement in laws and regulations. Judges in Vietnam have been reluctant to impose penalties or fines at levels sufficient to deter future infringements, and ex officio raids are sporadic at best. Piracy of copyrighted works and trademark counterfeiting remains rampant throughout Vietnam. Despite an extension of patent protection to 20 years, the U.S. pharmaceutical industry is concerned that there are no provisions in Vietnamese law to protect test data against unfair commercial use, which is a requirement under TRIPS and the BTA. Counterfeit pharmaceuticals are common in the marketplace. We encourage Vietnam to continue to build upon its public commitment to IPR protection by enacting strong IPR laws and providing effective enforcement against IPR infringement.

## **POSITIVE LIST OF DEVELOPMENTS: MAY 2004 - APRIL 2005**

### **2004**

#### **May**

In May 2004, China's State Council established an IPR Working Group within the Market Order and Rectification Office (MORO) made up of 12 governmental agencies reporting to the Vice Premier to plan and coordinate nationwide efforts on IPR protection and monitor important cases. Counterpart organizations based on the national model have been set up in provinces as well as in many cities and counties.

In May 2004, an amendment to Hong Kong's Broadcasting Ordinance went into effect that also criminalized possessing or using illegal decoders for commercial purposes.

In May 2004, Iraq's Coalition Provisional Authority (CPA) issued orders 80, 81, and 83, updating Iraq's trademark, patent, and copyright laws.

In May 2004, Italy's Parliament passed the Urbani Law. The law criminalizes the exchanging of copyrighted works regardless of whether such file sharing is done for cash profit or simply for gain, such as downloading music, film, or software to avoid having to purchase a legitimate copy.

In May 2004, the New Korea Media Rating Board (KM RB) implementing regulations went into effect to halt fraudulent DVD and video registrations through the movie rating system.

In May 2004, a Mexican law was adopted granting the Mexican Consumer Protection Agency (PROFECO) Authority to take ex officio action against markets selling goods that represent a risk to consumers, such as adulterated alcohol. PROFECO can seize the goods and give them to IMPI (Mexican Institute for Industrial Property) or PGR [Attorney General's Office (Prosecutor)].

In May 2004, Rwandan authorities continued to work with representatives of Sara Lee Household and Body Care to investigate a report about an incoming shipment of counterfeit Kiwi brand shoe polish. The 12-ton shipment of contraband was tracked, seized, confirmed to be counterfeit, and destroyed.

In May 2004, implementing regulations for Uruguay's upgraded copyright law were approved.

In Vietnam in May 2004, Joint Teams from the Economic Police Department of the Ministry of Public Security and the Market Management Bureau raided three computer companies in Hanoi. Each company was fined more than USD \$ 8,000 for using pirated versions of Microsoft's operating system, Lac Viet Dictionary and Norton Anti-virus programs.

On May 1, 2004, Poland doubled its period of pharmaceutical data protection to six years to meet EU requirements.

In Mexico on May 12, 2004, a bill that places intellectual property crimes involving copyright violations under the same section of criminal law as organized crime entered into effect. The law allows prosecutors and judges to use the penal code for organized crime when taking legal action against intellectual property rights pirates and their organizations, sanctioning the use of investigative techniques such as wire taps and witness protection, along with prison sentences of 8-16 years.

Jordan acceded to the WIPO Performances and Phonograms Treaty on May 24, 2004. Jordan had acceded to the Copyright Treaty on April 27, 2004. However, a number of the Treaties' provisions still need to be implemented in Jordanian law and in accordance with the U.S.-Jordan FTA.

## **June**

In June 2004, the Parliament of the Bahamas passed its Copyright Amendment Act 2004, which narrowed the scope of its broadcast compulsory licensing regime. The Governor-General of the Commonwealth of the Bahamas Copyright Act assented to the act on June 24, 2004. The Amendment will be gazetted when it is fully implemented by the Government of the Bahamas. As of April 2005, this amendment still has not been implemented.

In June 2004, the French Government launched a major initiative to fight piracy and counterfeiting. The initiative, which has been well coordinated with industry, focuses on improved domestic customs enforcement and increased international cooperation, within the EU and with third countries and involves a major public awareness campaign.

Korea acceded to the WIPO Copyright Treaty (WCT) in June 2004.

The U.S.-Morocco FTA was signed in June 2004.

In June 2004 in Lagos, Nigeria, duplicating equipment worth over \$5 million was seized. The Nigerian Police and the NCC have raided enterprises producing and selling pirated software and videos, and a number of businesses have filed high-profile charges against IPR violators.

The Philippine Presidential Anti-Organized Crime Commission (PAOCC) filed a criminal complaint in June 2004 against three prominent local shopping mall operators for violation of the Intellectual Property Code of the Philippines. This is apparently the first criminal Complaint of its kind filed by a Philippine law enforcement agency.

In June 2004, The Government of Thailand initiated an intellectual property rights enforcement campaign.

Andorra became party to the Berne Convention for the Protection of Literary and Artistic Works on June 2, 2004.

On June 7, 2004, Vietnam's president issued Resolution No. 332/2004/QD-CTN on adhering to the Berne Convention on Copyright Protection for Literary and Artistic Works.

Syria became party to the Berne Convention for the Protection of Literary and Artistic Works on June 11, 2004.

On June 15, 2004, Vietnam's National Assembly Passed a Civil Procedure Code. The Civil Procedure Code, which went into effect on January 1, 2005, regulates resolution of civil cases including intellectual property rights-related cases.

Kyrgyzstan became party to the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (Madrid Protocol) on June 17, 2004

On June 25, 2004, Russia's Prime Ministerial Commission for Protection of IPR held its first meeting under recently appointed Prime Minister Fradkov. The Commission continues to meet regularly.

Namibia became party to the Madrid Agreement Concerning the International Registration of Marks (Madrid Agreement) and the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (Madrid Protocol) on June 30, 2004.

## **July**

In July 2004, China's Customs General Administration issued new implementing regulations, which reduced the bond requirements for custom seizures of goods valued over RMB 20,000. The new implementing regulations also broadened the definition of bond to allow for a guarantee provided by a bank or a non-bank financial institution not just a cash bond.

In July 2004, the Government of Hong Kong successfully prosecuted an offender for selling illegal decoders, using the amendment to the Broadcasting Ordinance that went into effect in May, 2004 and sentenced him to three month's imprisonment. It was the first such criminal prosecution in Hong Kong.

In July 2004, Hong Kong's Customs and Excise Department used the Organized and Serious Crimes Ordinance (OSCO) to freeze the assets of a pirating syndicate worth \$2.7 million. This is the first time OSCO has been applied to an intellectual property rights case.

In mid-July 2004, Jordan's Parliament began debate on amendments to the copyright law intended to comply with the Free Trade Agreement-compliant amendments to the law. The Government of Jordan passed the proposed amendments in December 2004, which now await a decision by the King whether to sign them.

In July 2004, Pakistan acceded to the Paris Convention for the Protection of Industrial Property.

In July 2004, the Government of Peru passed Law No. 28289, the law on the fight against piracy, which increased the minimum penalty for piracy from a two-year to a four-year sentence, with a maximum sentence of eight years.

In July 2004, the Government of Peru passed a law requiring that SUNAT, Peru's Tax and Customs Agency, establish an import registry for all persons and companies importing blank optical discs and recording equipment.

The Serbia and Montenegro State Union parliament passed a new patent law in July 2004.

In July 2004, Singapore's amendments to the Trademarks Act, the Patents Act, a New Plant Varieties Protection Act, and a New Manufacture of Optical Discs Act came into effect, meeting the timeline for such acts in accordance with its U.S.-Singapore FTA Commitments.

In July 2004, revisions to Taiwan's patent law took effect, which simplified filing procedures.

In Estonia on July 1, 2004, the New Criminal Procedure Act entered into force. Under the new legal act, corporate entities can now be considered injured parties, allowing producers to file criminal claims, in addition to civil claims, for IPR infringements.

On July 3, 2004, Saudi Arabia's Ministerial Decision No. 1277, Regulations of Border Procedures for Protection of Intellectual Property Rights of Trademarks and Copyrights was published and went into effect on October 3, 2004. This decision empowers the customs authorities, part of the ministry of finance, to suspend the clearance of goods and to dispose of goods infringing on intellectual property rights.

The United Arab Emirates became party to the Berne Convention for the Protection of Literary and Artistic Works and the WIPO Copyright Treaty on July 14, 2004.

On July 14, 2004, Vietnam's Ministry of Science and Technology issued Instruction No. 18/2004/CT-BKHHCN with the intent to strengthen intellectual property rights enforcement and oversight of the quality of domestic, import and export goods. The instruction requires inspectors to monitor and resolve administrative breaches of intellectual property rights.

On July 20, 2004, Russian President Putin signed into law amendments to Russia's Copyright Law. Among the primary features of this law are the recognition and protection of pre-existing works and sound recordings, as required by Russia's obligation under the Berne Convention and the 1992 U.S.-Russia bilateral trade agreement and the adoption of provisions prohibiting the circumvention of technological protection measures and the trafficking in devices and services used to circumvent.

## **August**

In August 2004, China's State Council announced a year-long campaign targeting IPR infringement which it said would focus on import/export activities, trade fairs and exhibitions, distribution, wholesale markets, processing of brand name goods, and publishing. This campaign seeks to integrate the work of multiple government agencies in order to combat IPR abuses in fifteen provinces and cities designated for priority action, both for enforcement and education purposes. Various ministerial and local action plans have also been adopted.

In August 2004, the first U.S.-China joint investigative effort, dubbed “Operation Spring,” resulted in the shut down of a DVD export ring, arresting six people (including two Americans) while seizing more than \$83,000 in cash and more than 200,000 DVDs. This is notable for the cooperation between U.S. Immigration and Customs Enforcement (ICE) and Chinese Ministry of Public Security (MPS) authorities. International press reports and positive television coverage have drawn attention to this case.

In August 2004, the Kuwaiti Government submitted a draft law to the National Assembly that would make some improvements, including small increases in penalties for those convicted of violating intellectual property rights, and provisions to deal with some digital issues such as communication to the public/making available and protection for technological protection measures.

In August 2004, the Government of Mauritius amended the Customs Act to enable Customs to intercept counterfeit and pirated products entering Mauritius.

In August 2004, Taiwan’s legislature passed a number of corrective improvements to a copyright amendment passed the previous year, including (a) restoring provisions prohibiting the circumvention of technological protection measures; (b) restoring most of the heavier criminal penalties recommended by the Executive Yuan; (c) authorizing Taiwan Customs to take ex officio action, and removing the “intent to profit” criteria from the prior amendment.

In August 2004, Taiwan authorities, in close cooperation with industry, raided an optical media burning lab, seizing 228 CD-R burners and 49 DVD-R burners with the capability of producing \$47 million worth of pirated product annually.

In August 2004, Vietnam’s Office of the Government issued Official Letter No.3985/VPCP-KG containing the Prime Minister's approval for most to draft new intellectual property rights and technology transfer laws.

Costa Rica signed the U.S.-Dominican Republic-Central America Free Trade Agreement (CAFTA-DR) on August 5, 2004.

The Dominican Republic signed the U.S.-Dominican Republic-Central America Free Trade Agreement (CAFTA-DR) on August 5, 2004.

Guatemala signed the U.S.-Dominican Republic-Central American Free Trade Agreement (CAFTA-DR) on August 5, 2004.

Syria became party to the Madrid Agreement Concerning the International Registration of Marks (Madrid Agreement) and the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (Madrid Protocol) on August 5, 2004.

In August 2004, a Russian court sentenced a pirate to a prison sentence of three years for DVD piracy. This was the first non-suspended prison sentence for piracy in almost three years.

In August 2004, Russian President Putin signed a law on commercial secrets, which provides for physical protection of proprietary commercial information from misuse by government employees.

In August 2004, the Vietnamese Ministry of Home Affairs approved the establishment of the Vietnam Literature Copyright Centre (VLCC). VLCC is a non-governmental and non-profit organization under the management of Vietnam writers' association. VLCC's stated purpose is to execute the contracts on copyright transfer between the center and authors; to help settle disputes among members; and, to coordinate with relevant international organizations in protecting literary copyright. VLCC also disseminates copies of laws, regulations and international conventions on copyright for literary works to its members, writers and the general public.

### **September**

In September 2004, the Estonian Parliament adopted the amendment law to the Copyright Act (ALCA), which came into force on November 11, 2004. The ALCA amended the law in order to harmonize it with the European Information Society Directive 2001/29/EC, thus improving its substantive provisions along the lines of the obligations in the WIPO Internet Treaties.

In September 2004, the German Justice Ministry issued a first draft of its "second basket" of amendments to the copyright act. The "second basket" is designed to cover issues left over from the 2003 amendments that implemented the WIPO Internet Treaties.

In September 2004, the Government of Hong Kong prosecuted a business software end-use piracy case, winning guilty pleas from two of the defendants.

Paraguay's Specialized Technical Unit (UTE), which is part of the Ministry of Industry and Commerce (MIC) and supported by State Department INL funds, has stepped up enforcement efforts and cooperation with other parts of the Government of Paraguay, with the private sector and with neighboring countries. In September 2004, the Government of Paraguay issued a decree formally placing the unit within the Ministry of Industry and Commerce and narrowing its scope to focus on copyright piracy and falsification. In the past year, the unit has conducted 43 different operations targeted at importers and distributors of pirated and counterfeit goods.

In September 2004, Saudi Arabia's new patent law came into effect, replacing the 1989 law. The law covers patents, the lay-out design of integrated circuits, a variety of agricultural plants, and industrial designs.

### **October**

In October 2004, the Egyptian Ministry of Agriculture established a new plant variety registration office.

In October 2004, the Estonian Police, Customs and Tax Board, and the Border Guard Established a working group at the director general level to analyze information related to organized crime, including IPR-related offenses.



In October 2004, Israel's Ministry of Justice made a formal commitment to the USG to uphold the principals of national treatment for phonographic rights holders. This commitment protects the vast majority of "U.S." sound recordings, however the draft copyright legislation has not been formally amended to reflect the commitment.

Korea agreed to participate in the U.S. Strategy Targeting Organized Piracy (STOP!) initiative in October 2004.

The European Community became party to the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (Madrid Protocol) on October 1, 2004.

In October 2004, Sri Lankan police conducted their first high-profile IPR raid, of a counterfeit CD/DVC manufacturing plant.

In October 2004, the Government of Vietnam issued Decree No.175/2004/ND-CP on violations and administrative sanctions in the trade domain. Articles 18 and 19 of this decree detail sanctions for trading in fake goods, stamps, labels and packages and establish procedures for assessing fines for these acts. These articles also provide for additional measures such as seizure of equipment used for infringement; destruction of counterfeit goods; and, confiscation of illegal profit.

In October 2004, the Government of Indonesia passed optical disc regulations. The regulations require optical disc production facilities to use only moulds with engraved government approved SID codes, maintain production and licensing records, and submit to unannounced inspections. The optical disc regulations also provide enforcement through possible administrative sanctions and criminal penalties for copyright violators of up to five years in prison.

In October 2004, a Dominican Republic court decision against Channel 5/Telemicro for broadcast piracy obligated the company to pay a total of Rd Pesos 415,000 (approximately US \$14,000) to Twentieth Century Fox, Tri-star Pictures, Columbia Pictures, and Warner Brothers. The court sentenced Telemicro's manager to three months in prison, but these sentences have not been imposed, pending appeal.

Vietnam became party to the Berne Convention on Copyright Protection for Literary and Artistic Works on October 26 2004.

## **November**

In November 2004, China's Ministry of Public Security (MPS) began a new enforcement campaign, Operation Mountain Hawk. It provides guidance for the national police to work with the local police on accepting and investigating more cases, and reporting their results. The MPS held a kick-off seminar with the Quality Brands Protection Committee in December 2004 to show how MPS and local leaders from the Economic Crimes Enforcement Division of the Public Security Bureau are coordinating on IPR enforcement.

In November 2004, the U.S. Department of Commerce and China's Ministry of Commerce established a case review mechanism whereby U.S. companies reporting Chinese IPR violations

receive an interagency review and if enough evidence is collected, the case is brought to the attention of the Ministry of Commerce through our trade facilitation office in Beijing. The first case passed to the Chinese was from the NBA and without prompting was brought up to Secretary Evans by Vice Premier Wu Yi at their meeting this January.

In November 2004, the Cyprus police formed a dedicated unit specializing in intellectual property rights enforcement.

In November 2004, Korea's Ministry of Foreign Affairs and Trade co-sponsored an IPR Roundtable that brought together 80 rights holders, Korean Government officials, academics, and lawyers to discuss the legal and enforcement challenges of protecting IP in the digital age. U.S. Ambassador Christopher Hill and Korea's Trade Minister Kim Hyun-Chong delivered keynote addresses and senior National Assemblyman Lee Jong-Kul emphasized the importance of IPR protection during a speech.

In November 2004, the Kuwaiti Ministry of Commerce and Industry seized 32,000 DVDs and CDs were seized from Fsanta Musica Publications.

In November 2004, Nicaragua established a collective action society named Nicautor, which was authorized in December 2003 by Nicaragua's National Assembly. Nicautor is expected to strengthen the collection of copyright royalties for both foreign and Nicaraguan authors, especially of recorded works, and have the legal authority to bring lawsuits on behalf of member artists.

In Thailand during November and December 2004, the Royal Thai Police conducted dozens of factory and warehouse raids, seizing millions of pirate optical discs and decommissioning several replication machines used for copyright infringement.

In Vietnam during November 2004, Inspectors from Ministry of Culture and Information (MOCI), Ministry of Science and Technology and the Economic Police Department of the Ministry of Public Security raided two large computer suppliers in Hanoi and Ho Chi Minh City.

Kazakhstan became party to the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty on November 12, 2004.

In Nigeria on November 23, 2004, the Federal High Court of Enugu State issued an interim injunction against several firms infringing a Honeywell International trademark for spark plugs. The court warned all distributors, dealers, and retailers in Nigeria that the unauthorized use of Honeywell's "Autolite" trademark is illegal and constitutes an offense punishable by fine or imprisonment.

Bhutan became party to the Berne Convention for the Protection of Literary and Artistic Works on November 25, 2004.

## **December**

In December 2004, China released new judicial interpretations on the IPR sections of their Criminal Code lowering the minimum thresholds required for criminal convictions against IPR violators. It remains to be seen if the new judicial interpretations will result in more criminal convictions or more convictions with higher sentences and have the intended affect of reducing infringement and piracy rates. The critical issue remains that China needs to assert the political will to enforce its IPR laws via administrative referrals to criminal prosecution, as well as criminal investigations, prosecutions and convictions.

In December 2004, Estonian police and customs signed a cooperation agreement on information exchange.

In December 2004, the Greek Government held an anti-piracy workshop in Thessaloniki in conjunction with the U.S. Mission and the Motion Picture Association of America Greece Office. Thessaloniki has become a piracy hub and the successful workshop raised awareness of the scope of the problem in Northern Greece and laid the groundwork for a follow-on Anti-Piracy Task Force. A week after the program, a police raid in two warehouses uncovered over 13,000 counterfeit CDs and over 500 pirated DVDs peddled on the streets of Thessaloniki.

In December 2004, Hong Kong's Customs and Excise Department established a task force to monitor and crack down on peer-to-peer (P2P) piracy over the Internet. In January 2005, the task force arrested a man in Hong Kong for uploading three U.S. movies to the Internet.

In December 2004, Kuwaiti Customs raided a huge DVD-R production operation, the first discovered in the Middle East.

In December 2004 the Kuwaiti Ministry of Commerce and Industry seized 10,000 DVDs and CDs from 10 Kuwaiti stores.

In Mauritius in December 2004, at the request of U.S. company Oakley, the Customs Department and the Police Anti-Piracy Unit carried out a "cleaning" exercise against counterfeit Oakley sunglasses in the local market, confiscating over \$35,000 worth of counterfeit goods.

In December 2004, Moroccan Parliament passed amendments to its existing intellectual property legislation that brings Morocco into compliance with many of its TRIPs commitments.

Paraguay's Specialized Technical Unit (UTE) conducted a significant raid in Ciudad del Este in December 2004, one of 43 different operations in 2004 targeting importers and distributors of pirated and counterfeit goods.

In December 2004, Peru's National Police raided a Lima shopping center where pirated goods are sold, confiscating over \$500,000 in pirated DVDs and CDs.

In December 2004 the Serbia and Montenegro State Union parliament passed a package of four new WTO TRIPs-compatible laws providing protection for copyrights, trademarks, designs, and topographies of integrated circuits.

In December 2004, Spain announced key aspects of its new Integrated Plan for the Reduction and Elimination of Activities Violating Intellectual Property, which includes the creation of an interministerial commission involving 11 ministries and private sector representatives, preventative actions and public campaigns against piracy, an analysis of the efficacy of existing Spanish legislation, an emphasis on more effective police action and prosecution of street piracy, and the creation of mechanisms for training officials involved with combating IPR violations.

In December 2004, Taiwan Customs, with the assistance of Taiwan's Aerial Policy Bureau, seized over 1,800 counterfeit video game semiconductor chips and PC boards bound for mainland China.

On December 5, 2004 the Kuwaiti Ministry of Commerce and Industry conducted raids on 17 local shops, resulting in the seizure of 182,139 DVDs and CDs, including 62,000 from one store alone.

San Marino became party to the Patent Cooperation Treaty (PCT) on December 14, 2004.

In December 2004, Estonia's new civil court procedure act, which provides law enforcement agencies with the right to perform ex parte searches, passed its second reading in the Parliament.

In December 2004, the Government of India issued an ordinance to amend its current Patent Act. Effective January 1, 2005, India expanded product patent coverage to include pharmaceuticals and agro-chemicals.

In December 2004, Vietnam's Ministry of Science and Technology and the Ministry of Finance Issued Inter-ministerial Circular No.129/2004/TTLT/BTC-BKHCN on border control measures for industrial property of import and export goods. This circular authorizes intellectual property rights holders and their representatives to file petitions for applying border control measures for intellectual property if they find evidence of infringement.

In December 2004, Vietnam's Ministry of Finance issued Circular 132/2004/TT-BTC providing guidelines for the collection, payment, control and utilization of industrial property fees and charges. Circular 132 established one set of fees and charges for industrial property protection and services for all Vietnamese and foreign entities and individuals.

## **2005**

### **January**

In January 2005, in Beijing, the third annual Ambassador's IPR Roundtable brought together both USG, Chinese, EU, and Japanese officials with business and industry representatives to discuss the new judicial interpretations on the IPR section of China's criminal code presented by the Supreme People's Court, and Chinese IPR enforcement activities. Vice Premier Wu Yi delivered opening remarks and Secretary Evans gave an address.

Pursuant to its TRIPS obligation, Egypt opened its patent mailbox on January 1, 2005.

In January 2005, a man in Hong Kong was arrested by the Customs and Excise Department for uploading three U.S. movies to the Internet. The Customs and Excise Department has set up a joint task force with copyright industry representatives and Internet service providers to track down on-line pirates engaged in unauthorized file-sharing.

Korean courts in January 2005 issued five rulings on the unauthorized use of sound recordings by online music providers that resulted in fines and prison terms for online operators, stemming from violations of sound recording producers' reproduction rights. A judge ruled in one case that three users who downloaded and shared music files from the music site Soribada were liable for infringement of reproduction rights under the Copyright Act, thus marking the first time a Korean court has held users liable for P2P file sharing.

In January 2005, Korea revised its Copyright Act by granting sound recording producers and performers certain exclusive transmission rights. It also issued interpretations of the new legislation that may help the music industry in its legal battles against downloading, uploading, and exchanging computer files of sound recordings without the permission of rights holders.

In January 2005, Singapore's amended copyright law came into force, addressing a number of the legal reforms required for compliance with the US-Singapore Free Trade Agreement.

In January 2005, Taiwan's legislature approved a bill to prevent unfair commercial use of pharmaceutical test data for new drugs for a period of five years.

In January 2005, a special unit in charge of IPR-related issues was created within Uruguay's Organized Crime and Intelligence Branch of the police.

In January 2005, the Government of Australia entered into force the U.S.-Australia Free Trade Agreement under which it introduced a range of amendments to Australia's Copyright Act 1968 and committed itself to ratifying certain international intellectual property agreements such as the two WIPO Internet Treaties (WCT and WPPT). These amendments included: 1) new rights--both economic and moral--for performers in sound recordings and live performances; 2) extension of protection for most copyright material from 50 to 70 years after the death of the author; 3) greater use of criminal law, in addition to civil remedies, to enforce copyright; 4) increasing prohibitions to the non-commercial use of infringing material; 5) increased liability for end-users and consumer; and 6) broader protection for electronic rights management information.

In January 2005, Paraguay's new patent law (originally passed in 2000) came into force. The new law provides for the granting of pharmaceutical product patents and the Government of Paraguay hired and has been training two patent examiners to implement the law. The GOP also introduced legislation in late 2004 to increase prison terms for piracy and falsification.

In January 2005, Vietnam's Ministry of Home Affairs approved establishment of the Vietnam Anticounterfeit and Intellectual Property Protection Association of Foreign-Invested Enterprises (VACIP). This organization will serve as a forum for foreign invested enterprises to share experiences and strategies to deal with counterfeiting and piracy issues in Vietnam.

In January 2005, Uzbekistan deposited its instrument of accession to the Berne Convention for the Protection of Literary and Artistic Works. Nonetheless, Uzbekistan requested a reservation to the retroactivity provisions in Article 18 of the Berne Convention. The Berne Convention entered into force, with respect to the Republic of Uzbekistan, on April 19, 2005.

Botswana became party to the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty on January 27, 2005.

## **February**

In February 2005, the U.S. Foreign Commercial Service, the U.S.-Vietnam Trade Council and the HCMC General Sciences Library organized a workshop on the translation and reproduction of copyrighted literary works. The workshop was well attended by both local Vietnamese and foreign publishers, who clarified licensing procedures and discussed current challenges to licensing U.S. books in Vietnam. The workshop also included time for local publishers to meet with representatives from major foreign publishing houses to negotiate the terms for obtaining a license to translate or reproduce texts in Vietnam.

In February 2005, the Philippines Congressional Oversight Committee on the Optical Media Board approved the implementing rules and regulations for the Optical Media Act (enacted in February 2004). The passage of the rules and regulations represent the first concrete congressional action on IPR since the passage of the Optical Media Act.

Indonesia became party to the WIPO Performances and Phonograms Treaty on February 15, 2005.

In February 2005, Kazakhstan financial police announced the beginning of criminal proceedings in Almaty in a significant software piracy case. The alleged violator was installing unlicensed Microsoft programs on computers he was selling.

## **March**

In March 2005, the Egyptian Government provided training to inspectors working on trademark enforcement.

Japan joined the United States in March 2005 in co-sponsoring an initiative in APEC aimed at reducing trade in counterfeit and pirated goods as well as on-line piracy.

In March 2005, Hong Kong's Customs and Excise Department cracked its largest-ever corporate piracy case, arresting two men and confiscating 16 computers that had pirated graphic design programs worth more than \$1 million installed on them.

In March 2005, Saudi Arabian Ministry of Interior conducted a major and successful raid in the Al Batha area in Riyadh. \$1.2 million worth of audio-visual materials were seized and more than 250 people arrested.

Armenia became party to the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty on March 6, 2005.

Brazil's National Council to Combat Piracy and Intellectual Property Crimes adopted a National Action Plan on March 17, 2005. The Plan has been posted on the website of the Brazilian Ministry of Justice to facilitate monitoring of the Plan's implementation. The Plan was adopted through a consensus process that included Brazilian representatives of the interested copyright and trademark sectors.

In Taiwan on March 18, 2005, the Taipei City Police with cooperation from industry raided a pirate CD-R lab seizing 93 optical disk burners and arresting three people.

Macedonia became party to the WIPO Performances and Phonograms Treaty on March 20, 2005.

On March 23, 2005 India's parliament completed its action to make permanent the change to India's patent law, which had been introduced by temporary ordinance in December 2004. The Indian President signed the patent amendment bill on April 5, 2005.

#### **April**

In April 2005, Vice Premier Wu Yi announced that the special IPR protection campaign originally scheduled to end in September would be extended to the end of the year. Wu Yi stated that the next stage of the nation-wide campaign would focus on the infringement of food and pharmaceutical trademarks, as well as well-known trademark infringements, and would target street vendors of illegal publications, audio-visual products and software. Wu Yi also set a goal of eliminating all counterfeit office software usage in government offices above the prefectural and municipal levels.

In April 2005, the Egyptian Government issued the third and last chapter of the executive (implementing) regulations of Egypt's new IPR law. This chapter of the IPR law governs copyright protection and was issued back in 2002.

In April 2005, Egypt joined the WIPO Nice Agreement Concerning The International Classification Of Goods And Services For The Purpose Of Registration Of Marks.

In April 2005, Kuwait's Ministry of Information participated in raids against 14 locations that the copyright industry had identified as being involved in pirate activities and found 11 of them to be in violation of Kuwaiti law. The pirated goods were seized and the proprietors have been referred to the public prosecutor's office for legal action.

Comoros became party to the Patent Cooperation Treaty (PCT) on April 3, 2005.

In April 2005, in Brazil, the Sao Paulo Anti-piracy police unit (DEIC), supported by APDIF do Brazil, raided an Industrial CD plant named DIGIMATIC Oficina Replicadora Ltda, in the city of Santana do Parnaíba, 60 kilometers from Sao Paulo. The plant had one active line. Arrested at the plant was Mohd Hasan Tawfic Mohd, a Lebanese national. Two others were held for

questioning pending further investigation. Seized were 52,380 CDs mainly of Brazilian repertoire and 27,900 play-station CDs. The plant was fully equipped with industrial recording machinery with a capability of producing 20,000 CD's daily.

In April 2005, there was a seizure of approximately 20,000 pirate CDs and DVDs in Honduras. Following the seizures, several suspects were arrested in raids on more than half a dozen sales locations in the cities of Tegucigalpa and Choluteca.

In April 2005, Indonesia Police seized 2 million locally produced pirated Play Station 2 DVDs intended for export.

Comoros became party to the Berne Convention for the Protection of Literary and Artistic Works on April 17, 2005.

Singapore became party to the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty on April 17, 2005.

In April 2005, Indonesia's optical disc regulations went into effect.



**WIPO Internet Treaties:  
WIPO Performance and Phonograms Treaty (WPPT)  
and the WIPO Copyright Treaty (WCT)**

The following became parties to the World Intellectual Property Organization (WIPO) Performances and Phonograms Treaties (WPPT) during May 2004-April 2005. The WPPT entered into force on May 20, 2002.

Jordan	May 24, 2004
Kazakhstan	November 12, 2004
Botswana	January 27, 2005
Indonesia	February 15, 2005
Armenia	March 6, 2005
(The Former Yugoslav Republic of) Macedonia	March 20, 2005
Singapore	April 17, 2005

The following became parties to the World Intellectual Property Organization (WIPO) Copyright Treaty (WCT) during May 2004-April 2005. The WCT entered into effect on March 6, 2002.

Republic of Korea	June 24, 2004
United Arab Emirates	July 14, 2004
Kazakhstan	November 12, 2004
Botswana	January 27, 2005
Armenia	March 6, 2005
Singapore	April 17, 2005