

## **2004 SPECIAL 301 REPORT**

### **Executive Summary**

United States Trade Representative Robert B. Zoellick today announced the results of the 2004 "Special 301" annual review, which examined in detail the adequacy and effectiveness of intellectual property protection in approximately 85 countries.

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

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

The Special 301 report addresses significant concerns with respect to such trading partners as Argentina, The Bahamas, Brazil, Egypt, India, Indonesia, Israel, Korea, Kuwait, Lebanon, Pakistan, Paraguay, The Philippines, Poland, Russia, Taiwan, Thailand, and Turkey. In addition, the report notes that the United States will consider all options, including but not limited to initiation of dispute settlement consultations, in cases where countries do not appear to have implemented fully their obligations under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).

In this year's review, USTR devotes special attention to the increasingly important issue of the need for significantly improved enforcement against counterfeiting and piracy, with particular emphasis on the ongoing campaign to reduce production of unauthorized copies of "optical media" products such as CDs, VCDs, DVDs, and CD-ROMs. Counterfeiting of trademarked goods is an increasing problem in many countries, including Brazil, Bulgaria, India, Indonesia, Lebanon, Mexico, Pakistan, Paraguay, The Philippines, Russia, Venezuela, and Vietnam. The issue in these and other countries ultimately is one of the foreign government's political will to effectively address piracy and counterfeiting. The annual Special 301 process and report send a message to the governments of countries where serious IP-related problems exist. In addition, USTR continues to focus on other critically important issues, including internet piracy, proper implementation of the TRIPS Agreement by developed and developing country WTO Members, and full implementation of TRIPS standards by new WTO Members at the time of their accession. USTR also continues to encourage countries to ensure that government ministries use only authorized software.

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

The United States is committed to a policy of promoting increased intellectual property protection. In this regard, we are making progress in advancing the protection of these rights through a variety of mechanisms, including through the negotiation of free trade agreements (FTAs). We are pleased that the recently concluded FTAs with Central America including the Dominican Republic, Morocco and Australia will strengthen the protection of IPR in those countries. Specifically, the intellectual property chapters of these agreements provide for higher levels of intellectual property protection in a number of areas covered by the TRIPS Agreement. We are also seeking higher levels of protection and enforcement in the FTAs that are currently under negotiation with Bahrain, Panama, the Southern Africa Customs Union, in the upcoming FTA negotiations with Andean countries and Thailand, and in the ongoing negotiation of a Free Trade Area of the Americas. Another opportunity we are using to strengthen the protection and enforcement of intellectual property is the increasing number of trade and investment framework agreement (TIFA) negotiations with several countries in regions such as the Middle East and Asia.

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

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

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

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

Piracy and counterfeiting of copyrighted products in digital, print (e.g., books, journals and other printed materials) and other analogue formats, as well as counterfeiting of all types of trademarked products, have grown to such a scale because these illegal activities offer enormous profits and little risk for the criminal element of society. Criminals can get into the counterfeiting business with little capital investment, and even if caught and charged with a crime, the penalties actually imposed in many countries are so low that they offer no deterrent.

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

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

This is why USTR seeks through our FTAs and our bilateral consultations to ensure that criminal penalties are high enough to have a deterrent effect, both in the law and as imposed by the courts and administrative bodies, as well as to ensure that pirated and counterfeit products, and the equipment used to make them, are seized and destroyed. These products can be produced and sold at prices much lower than legitimate products, but still deliver attractive profit margins for the infringer because the counterfeit and pirated products are usually made with substandard materials, and undergo little or no quality control or even basic health and safety testing. The economic damage caused by counterfeiting to the legitimate companies whose products are counterfeited is enormous. Losses to U.S. industries alone are estimated at \$200 to \$250 billion per year.

### **Controlling Optical Media Production**

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

Governments, such as those of Hong Kong and Macau that implemented optical media controls in previous years have clearly demonstrated their commitment to continue to enforce these measures. Taiwan and Malaysia are steadily improving their enforcement as well. The effectiveness of such measures is underscored by the direct experience of these governments in successfully reducing pirate production of optical media. We continue to urge our trading partners facing the threat of pirate optical media production within their borders to adopt similar controls or aggressively enforce existing regulations in the coming year.

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

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

Developed countries were required to fully implement TRIPS as of January 1, 1996, while developing countries were given a transition period – until January 1, 2000. Ensuring that developing countries are in full compliance with the Agreement now that this transition period has come to an end is one of this Administration's highest IPR priorities. With respect to least developed countries, and with respect to the protection of pharmaceuticals and agriculture chemicals in certain developing countries, even longer transitions are provided.

Developing countries continue to make progress toward full implementation of their TRIPS obligations.

Nevertheless, certain countries are still in the process of finalizing implementing legislation and establishing adequate enforcement mechanisms. Every year the U.S. Government provides extensive technical assistance and training on the implementation of the TRIPS Agreement, as well as other international intellectual property agreements, to a large number of U.S. trading partners. Such assistance is provided by a number of U.S. Government agencies, including the U.S. Patent and Trademark Office, the U.S. Copyright Office, the State Department, the U.S. Agency for International Development, the U.S. Customs and Border Protection, the Justice Department, and the Commerce Department's Commercial Law Development Program on a country-by-country basis, as well as in group seminars, including those co-sponsored with the World Intellectual Property Organization (WIPO) and the WTO. Technical assistance involves review of, and drafting assistance on, laws concerning intellectual property and enforcement. Training programs usually cover the substantive provisions of the TRIPS Agreement, as well as enforcement. The United States will continue to work with WTO Members and expects further progress in the near term to complete the TRIPS implementation process. However, in those instances where additional progress is not achieved in the near term, the United States will pursue our rights through WTO dispute settlement proceedings.

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

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

However, because of the expense involved in producing the safety and efficacy data needed to obtain marketing approval, the TRIPS Agreement recognizes that the original applicant should be entitled to a period of exclusivity during which second-comers may not rely on the data that the innovative company has created to obtain approval for their copies of the product. During this period of exclusive use, the data cannot be relied upon by regulatory officials to approve similar products. This period of exclusivity is generally five years in the United States and six to ten years in the EC member States. Other countries that provide a period of exclusivity against reliance on data include Australia, China, the Czech Republic, Estonia, Japan, Jordan, Korea, Mexico, New Zealand, Slovenia, and Switzerland. We commend Bulgaria and Colombia on their recent implementation of data protection for pharmaceutical and agricultural chemical products, respectively. In addition, we commend Mexico for passage of regulations that strengthen the coordination between its health and patent agencies to protect valid patents of innovative pharmaceutical products. We urge all WTO members to swiftly complete their implementation of Article 39.3, including the rest of the Andean countries, Israel and Turkey.

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

---

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

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

The Internet has undergone explosive growth and, coupled with increased availability of broadband connections, serves as an extremely efficient global distribution network for pirate products. The explosive growth of copyright piracy on the Internet is a serious problem. We are continuing to work with other governments, and consult with U.S. industry, to develop the best strategy to address Internet piracy.

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

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

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

## **Other Initiatives Regarding Internet Piracy**

We are seeking to incorporate the highest standards of protection for intellectual property into appropriate bilateral and regional trade agreements that we negotiate. We have been successful in this effort by incorporating the standards of the WIPO Internet Treaties as substantive obligations in all our FTAs to date, and continue to pursue this goal in other FTAs currently under negotiation and yet to be launched. Moreover, our proposals in these negotiations will further update copyright and enforcement obligations to reflect the technological challenges we face today as well as those that may exist at the time negotiations are concluded.

## **Government Use of Software**

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

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

Turkey, and the United Kingdom. Ambassador Zoellick was pleased that these governments have recognized the importance of setting an example in this area and expects that these decrees will be fully implemented. The United States looks forward to the adoption of similar decrees, with effective and transparent procedures that ensure legitimate use of software, by additional governments in the coming year.

### **Intellectual Property and Health Policy**

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

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

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

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

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

### **Regulation and Sustainable Innovation**

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

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

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

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

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

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

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

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

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

### **WTO Dispute Settlement**

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

United States resorted to dispute settlement in August of 2003 by requesting the establishment of a Panel to examine the European Communities' discriminatory regime for protection of geographical indications for agricultural products and foodstuffs. The following section provides updates of this and previously announced WTO cases.

### **Argentina**

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

On the two outstanding issues, that of data protection and the ability of patentees to amend pending applications to claim certain enhanced protection provided by the TRIPS Agreement, the United States retained its right to seek resolution under the WTO dispute settlement mechanism while continuing to work toward a resolution with Argentina.

### **European Union**

At the conclusion of the 1999 Special 301 review, the United States initiated a WTO dispute settlement case against the EU, based on the apparent TRIPS deficiencies in EU Regulation 2081/92, which governs the protection of geographical indications (GIs) for agricultural products and foodstuffs in the EU. The regulation appears to deny national treatment to foreign GIs. According to the plain language of the regulation, only EU GIs may be registered. With respect to trademarks, the regulation permits dilution and even cancellation of trademarks when a GI is created later in time. Our initial WTO consultation request alleged that this regulation denies national treatment to foreign geographical indications, and does not provide sufficient protection to trademarks that are similar or identical to a GI and appears, therefore, in violation of the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). The United States requested consultations regarding this matter on June 1, 1999, and numerous consultations have been held since then.

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

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

### *Potential Dispute Settlement Cases*

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

The United States will consider all options, including but not limited to possible initiation of new WTO



dispute settlement cases, in working with these countries toward full TRIPS implementation. The United States will continue to consult in the coming months with all of these countries in an effort to encourage them to resolve outstanding TRIPS compliance concerns as soon as possible.

### STATUTORY AUTHORITY

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 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 this pool of countries has been determined, the USTR is required to decide which, if any, of these countries should be designated Priority Foreign Countries. Priority Foreign Countries are those countries that:

- (1) have 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) are 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, except that the maximum time for an investigation under Special 301 is shorter in some circumstances.

Today’s Special 301 announcement follows a lengthy information-gathering and negotiation process. The interagency Trade Policy Staff Committee that advises USTR on implementation of Special 301 obtains information from the private sector, U.S. embassies, the United States' trading partners, and the *National Trade Estimates* report.

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 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 avenues to pursue resolution of IPR issues. In issuing the announcement, Ambassador Zoellick is expressing the Administration’s resolve to take consistently strong actions under the Special 301 provisions of the Trade Act.

## **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 on January 23, 2002. These sanctions remain in effect based on the repeated failure of the Government of Ukraine to enact and enforce adequate optical disc media licensing legislation in order to fully 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 the law's inadequacies, but Ukraine's Rada has failed to pass these amendments on several occasions. As a result, Ukraine's law does not have adequate enforcement provisions to prevent unauthorized optical media production and distribution. Ukraine is also a major trans-shipment point and storage location for illegal optical media produced in Russia and elsewhere. While Ukraine has taken some steps to address its optical media piracy problem, border enforcement efforts remain weak and small criminal penalties for unauthorized production and export of CDs and CD-ROMs do not 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 U.S. firms remain concerned over the lack of cooperation by enforcement officials in combating counterfeiting activities. The United States urges the Ukrainian Government to pass amendments to its optical media law to provide for adequate enforcement. Ukrainian officials also must strengthen current enforcement efforts to deter optical media piracy and address trademark counterfeiting.

## **SECTION 306**

### **CHINA**

Addressing weak IPR protection and enforcement in China is one of the Administration's top priorities. At the April meeting of the Joint Commission on Commerce and Trade (JCCT), the United States secured a commitment from China's Vice Premier Wu Yi that China will undertake a series of actions to significantly reduce IPR infringements throughout the country. These actions are critical in light of the rampant counterfeit and piracy problems that plague China's domestic market, and because China has become a leading exporter of counterfeit and pirated goods to the world.

Prior to the JCCT, China issued several rules and other measures concerning IPR protection and enforcement. These include: Rules on the Determination and Protection of Well-Known Trademarks, Measures on the Implementation of the Madrid Agreement on Trademark International Registration, Measures on the Registration and Administration of Collective Trademarks and Certification Marks, Measures on the Implementation of Administrative Penalties in Copyright Cases, and Regulations on the Customs Protection of IPR. The new measures are generally positive developments. Further, China announced last fall the formation of a "Leading Group" on IPR to better coordinate policy and enforce IPRs across China. The Group, headed by Vice Premier Wu Yi, functions under the State Council and is composed of officials from 36 departments.

China made many commitments at the recent JCCT meetings intended to address our underlying concerns on IPR. Vice Premier Wu announced that China would undertake a series of near-term actions with the objective of significantly reducing IPR infringement levels. In particular, China will:

1. Promulgate a judicial interpretation before the end of the year from the Supreme People's Court

and the Supreme People's Procuratorate that:

- appropriately lowers thresholds for applying criminal sanctions for acts of IPR infringement; and
- stipulates guidelines for applying criminal sanctions for the import, export, storage, and transport of counterfeit and pirated products and for online piracy.

The new judicial interpretation is an attempt to remedy China's failure to make effective use of its criminal enforcement regime to address IPR issues. Administrative authorities routinely fail to refer cases involving commercial-scale IPR infringements for criminal investigation and prosecution. The number of criminal cases for counterfeit trademarks, while growing, remains inadequate, and the Government initiates very few criminal actions against copyright piracy. When such actions do result in convictions, the penalties applied are insufficient to deter further IPR infringement.

We have noted a number of significant deficiencies in China's application and interpretation of its Criminal Code. First, monetary value thresholds must be met before prosecutors will initiate a criminal investigation. These thresholds are too high, resulting in the failure of the Government to pursue criminal action against all commercial-scale infringements. Second, criminal prosecutors and/or courts impose, in some instances, extraneous proof-of-sale requirements. Third, criminal sanctions are seldom applied for cases involving import/export, transport, storage, and distribution of infringing goods. The problem of monetary value thresholds is exacerbated by the fact that valuation calculations are not usually done using the price of the legitimate good. We expect the new judicial interpretations to address all of these issues and generate stronger criminal sanctions against commercial-scale counterfeiters and pirates.

2. Continue and intensify a national campaign against IPR infringing activities including:
  - a crackdown on counterfeit trademarks, pirated audio-visual and software products, patent infringements, and other violations of IPRs;
  - investigation and issuance of criminal sanctions in a number of cases;
  - raids on the retailers of pirated CDs and DVDs;
  - closure of production enterprises engaged in counterfeiting and piracy; and
  - increased inspections of exports.

Retail sale and export of pirated and counterfeit products remains a significant problem in China. We expect this national campaign to bring about an immediate and noticeable improvement, and will monitor its implementation to determine whether it meets that expectation. In recent years, China has conducted large numbers of raids on suspected counterfeiters and pirates, but the penalties applied following such raids have not deterred infringement. We expect the new campaign to generate stronger administrative penalties and an increased number of referrals for criminal investigation and prosecution. These steps are needed if the intensified campaign is to have the desired effect of deterring future infringements.

3. Implement new customs regulations, increasing customs authorities' criminal enforcement actions against IPR-infringing imports and exports, and relax surety requirements.

New customs regulations came into effect on April 1, 2004, and we expect China to immediately take action to halt the growing stream of counterfeit and pirated goods being exported from China. In 2003 China accounted for 66 percent of all U.S. Customs and Border Protection seizures of IPR-infringing goods. China is also a major source of counterfeit and pirated exports to Japan, the EU, and other third-country markets. China fails to refer a sufficient number of cases involving export to criminal investigation and prosecution and also fails to pursue investigations to capture the producers of the counterfeit and pirated goods. We expect the new regulations to remedy this situation. Chinese Customs

is also relaxing its surety requirements; this move will facilitate the pursuit of investigations and judicial action. The Administration will monitor China's implementation of the new customs regulations and continue to work actively to clamp down on counterfeit and pirated Chinese exports at U.S. borders.

4. Accelerate efforts to ratify and join the WIPO Internet treaties.

Enacting legislation to implement these treaties would greatly improve the legal basis for enforcement against Internet piracy. China has a rapidly growing number of Internet users (believed to be the second or third highest in the world). China needs to strengthen the available tools for rights holders and enforcement authorities to combat an emerging frontier for IPR piracy.

5. Continue audits to implement the use of legitimate software, including extension of such efforts to include local urban governments.

We remain concerned that many Chinese enterprises, institutions, and other entities fail to use software in accordance with the terms of their license. Government institutions, at all levels, should set a positive example. This effort, by drawing in local urban governments, represents a further step to ensure that this is the case. While there were a small number of positive court rulings involving end-user piracy in 2003, significant problems remain. We urge China to accelerate its efforts to undertake criminal investigations and prosecutions to address such problems.

6. Conduct public education campaigns on the importance of IPR.

China will further intensify its efforts to increase awareness among Chinese consumers of the economic harm and potential health and safety risks that result from purchasing counterfeit and pirated products. IPR infringements hurt Chinese and foreign rights holders and damage the reputation of the "Made in China" brand. Fake Chinese-made automotive parts, pharmaceuticals, infant formula, and other counterfeit products have harmed consumers both in China and throughout the world.

Lastly, the JCCT established an IPR Working Group to discuss IPR issues, including monitoring the implementation of the commitments stated above.

We will also continue to press China to increase purchases of legitimate goods, both through its own government procurement and through a lowering of market access barriers.

The United States will continue to monitor China's actions to implement effectively its JCCT commitments, its WTO commitments, and the 1995 bilateral IP agreement with the United States (including additional commitments made in 1996). We will be conducting an out-of-cycle review in early 2005 to evaluate whether China is implementing its commitments and whether the actions undertaken are bringing forth substantial progress toward China's objective of significantly reducing its level of IPR infringement.

## **PARAGUAY**

Paraguay continues to have problems in providing protection to copyrights and trademarks, both with respect to poor internal enforcement and weak border enforcement. The USTR identified Paraguay as a Priority Foreign Country in January 1998 as part of a Special 301 out-of-cycle review. The subsequent 301 investigation terminated with the signing of a comprehensive Memorandum of Understanding (MOU) on the protection of intellectual property in 1998. That MOU expired and the U.S. and Paraguay

negotiated a new MOU in December 2003. We remain concerned over several issues, including: the involvement of organized crime in piracy and counterfeiting operations; the relatively few resources provided for criminal investigations and raids, and the attendant lack of those activities; and the lack of willingness on the part of the judiciary to impose deterrent sentences. We are encouraged by signs that the Duarte Administration, which took office in August 2003, has made IPR protection and enforcement a priority. The Government has taken some positive steps with regard to enforcement, but a great deal of improvement still needs to be made.

### **PRIORITY WATCH LIST**

#### **ARGENTINA**

Protection of intellectual property in Argentina has not improved significantly, therefore Argentina will remain on the Priority Watch List. The Government of Argentina did amend its patent law to provide protection for products obtained from a process patent, implementing the May 2002 U.S.-Argentina agreement, and put in place fast-track procedures for patent applications. However, Argentina's overall copyright, patent, and data protection regimes do not appear to comply with its international obligations. Copyright piracy for all industry sectors remains at high levels including recordable CDs (CD-Rs) and other optical media, entertainment software, sound recordings, books, and films. Although the willingness of the Argentine Government to initiate some enforcement actions during 2003 was encouraging, enforcement against piracy and counterfeiting remains lax and ineffective. Enforcement of copyrights on recorded music, videos, books, and computer software remains inconsistent, and inadequate resources, border controls and slow court procedures have hampered the effectiveness of enforcement efforts. In addition, unauthorized use of protected seed varieties remains a problem. In April 2002, the United States and Argentina reached an agreement with respect to most claims in a WTO dispute brought by the United States concerning Argentina's implementation of its TRIPS patent obligations. The important issue of data protection remains unresolved. Argentina still does not provide protection for confidential data submitted by research-based pharmaceutical companies and does not have a linkage system between the health agency and patent office, which results in the continued approval of copy products. The United States urges Argentina to implement its TRIPS obligation to provide data protection and an effective linkage system to protect patented pharmaceutical products. USTR will continue to monitor Argentina's efforts to effectively address these concerns, as well as its compliance with the commitments made under the May 2002 agreement.

#### **BAHAMAS**

The United States remains concerned over the lack of progress made by the Government of the Commonwealth of the Bahamas in fulfilling its obligations to address serious copyright concerns under an agreement reached between our two countries in 2000. Problems persist in the area of copyright protection for U.S. cable programs and motion picture copyrighted works. In particular, 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. Furthermore, the remuneration system for copyrighted works under the compulsory licensing program remains inadequate and arbitrarily includes even lower, special rates for hotels and other commercial enterprises. We understand that draft legislation for amendments to correct deficiencies in the copyright law have passed in the lower house of Parliament and is now in the Senate for consideration. The United States urges The Bahamas to work to fulfill its obligations under the agreement and promptly enact these necessary amendments to the copyright law. In

addition, the United States continues to encourage U.S. cable operators and copyright holders to enter into negotiations with licensed Bahamian cable operators to provide for the legitimate cable transmission of copyrighted works in the Bahamas.

## **BRAZIL**

Brazil continues to fall short in providing adequate and effective protection of IPR. Despite some positive developments, most notably with respect to the formation and activities of the Brazilian Congress' Chamber of Deputies' Commission of Parliamentary Inquiry on piracy and amendments to the criminal code, protection has not significantly improved. Brazil is one of the largest markets globally for legitimate copyrighted products, but also one of the world's largest pirate markets. Optical media piracy and Internet piracy are increasing. The U.S. copyright industry estimates that losses in Brazil are the largest in the hemisphere, with industry-estimated losses exceeding \$785 million in 2003. Despite having adopted modern copyright legislation, Brazil has not undertaken adequate enforcement actions against piracy. Criminal enforcement has not been sufficient or effective in deterring piracy. Furthermore, although a substantial number of raids are conducted by Brazilian police, very few result in prosecutions and convictions. Ineffective border enforcement that fails to stop an influx of pirated goods continues to plague trademark and copyright owners. Brazil has not made significant progress processing the backlog of pending patent applications, which industry estimates to be at 47,000 and for which industry has already paid substantial upfront processing fees. Unauthorized copies of pharmaceutical products continue to receive sanitary registrations that rely on undisclosed tests and other confidential data, although no unauthorized copies have been marketed yet. We will continue to monitor Brazil's progress in these areas, including through the ongoing GSP review that was initiated by USTR in 2001.

## **EGYPT**

Egypt was moved from the Priority Watch List to the Watch List in 2003, based in large part on the passage of a comprehensive new IPR law. The United States notes the Government of Egypt's passage of implementing regulations for three of the four chapters of the IPR law, and continuing efforts in enforcement. However, recent marketing approvals for locally produced copies of patented pharmaceutical products, as well as deficiencies in Egypt's copyright enforcement regime, judicial system and trademark enforcement necessitate the elevation of Egypt to the Priority Watch List. The United States is seriously concerned by the Egyptian Health Ministry's marketing approval of four copies of U.S. innovator drugs and approval of four additional applications to register and market innovator drugs on the basis of the U.S. firms' confidential test data. These approvals run counter to Egypt's own domestic laws and raise serious concerns about Egypt's commitment to protect confidential test data. Egypt's copyright enforcement remains weak with continued high losses to the book publishing industry, high corporate end-user piracy levels and lax enforcement against extensive commerce in pirated books, CDs, DVDs and VCDs.

Copyright enforcement is further impaired by the lack of implementing regulations for the copyright portion of Egypt's new IPR law, as well as a court system in which copyright cases continue to move slowly, collection of judgments is difficult and transparency is lacking. Companies continue to experience difficulties with Egypt's Trademark Law, which makes trademark enforcement very difficult. In addition, implementing regulations for the new IPR law's sections for patents, trademarks and botanical varieties do not appear to fully address the deficiencies and ambiguities in the law. Efforts by Egypt to address these problems and improve its IPR regime will continue to play an important role in the expansion of trade and investment ties with the United States.

## **EUROPEAN UNION**

The European Union (EU) will remain on the Priority Watch List because it has not demonstrated any willingness to address certain IP-related concerns in a sufficient manner, despite encouragement by the United States including through the U.S.-EU Trans Atlantic Economic Partnership. At the conclusion of the 1999 Special 301 review, the United States initiated a WTO dispute settlement case against the EU, based on the apparent TRIPS deficiencies in EU Regulation 2081/92 ("GI Regulation"), which governs the protection of geographical indications (GIs) for agricultural products and foodstuffs in the EU. The regulation appears to discriminate against non-EC nationals and products, thereby violating WTO obligations to provide national treatment and most-favored-nation treatment. Further, the GI Regulation appears to deny trademark rights to owners of registered trademarks, rights that the EC is obliged to provide under the TRIPS Agreement. Despite over four years of consultations since June 1999, we were unable to resolve this matter, and so, in August 2003, we requested the establishment of a WTO dispute settlement panel to review the consistency of the EC's GI Regulation with WTO rules. That proceeding is on-going. In addition, lack of full implementation of the EU Biotechnology Directive, which obligates EU Member States to reform national laws and practices to affirmatively provide patent protection for a broad range of biotechnology inventions, by several EU member states continues to be a concern.

## **INDIA**

While India has improved its IPR regime, protection of intellectual property in some areas remains weak due to inadequate laws and ineffective enforcement. India's 2002 patent law amendments (which became effective in May 2003) exempt subject matter such as biotechnological inventions, methods for agriculture and horticulture; processes for the treatment of humans, animals, or plants, and substances prepared by chemical processes from patent protection. Under the TRIPS Agreement, India has until January 1, 2005 to provide product patent protection, including for pharmaceuticals and agricultural chemicals. While the United States is encouraged by the Indian Government's recent statements concerning implementation of data exclusivity regulations, India has yet to implement the TRIPS obligation to protect confidential test data submitted by innovative pharmaceutical companies for market approval. India's Copyright Act has three overly broad exceptions, which together weaken protection of software. India is also in the process of revising its copyright law to implement the WIPO Internet treaties; we expect India to fully implement its obligations in this regard. Protection of foreign trademarks remains difficult due to procedural barriers and delays. Trademark owners must prove they have used their mark to avoid a counterclaim for registration cancellation due to non-use. Such proof can be difficult, given India's policy of discouraging foreign trademark use. Companies denied the right to import and sell products in India often are unable to demonstrate use of registered trademarks through local sale.

Piracy of copyrighted materials (particularly software, films, popular fiction and certain textbooks) remains a problem for U.S. and Indian rightholders. India has not adopted an optical disc law to deal with optical media piracy. Cable television piracy continues to be a significant problem, with estimates of tens of thousands of illegal systems in operation. The United States also has serious concerns about high levels of counterfeiting, particularly for medicines and auto parts. India's criminal IPR enforcement regime remains weak, and India needs sustained, centralized, coordinated enforcement of intellectual property rights, especially trademarks and copyrights. Its court system is extremely slow, and there are only a few reported convictions for copyright infringements resulting from raids. Industry reports significant weaknesses in India's border protection against counterfeit and pirated goods. India also needs to address the high volume of exports of domestically produced counterfeit goods.



## **INDONESIA**

Indonesia took steps in 2003 to strengthen its IPR regime, but progress, particularly in the area of enforcement against piracy and counterfeiting, has been inconsistent. Serious concerns remain over lack of enforcement; the production, distribution, and export of pirated optical media products; trademark infringement; and deficiencies in Indonesia's judicial system. Stern warnings of strong enforcement made by the Directorate General for IPR to mall owners in July 2003 led to a near-complete shutdown of pirate vendors for 30 days, demonstrating that effective enforcement can stop pirates. However, lack of follow-through resulted in a return to high levels of activity by retail pirate vendors. Indonesia carried out some raids against retail outlets for pirate optical media products in 2003, but enforcement and prosecution of IPR violations remained insufficient. Pirate optical media products, including CDs, VCDs, DVDs and CD-ROMs, still dominate Indonesia's market. At least 27 plants in Indonesia produce optical media products. With a total annual disc capacity of 108.5 million, domestic production of pirated products continues to increase. The pharmaceutical industry has estimated that counterfeit drugs account for 30-40 percent of Indonesia's market, and there are serious concerns about imports of pirated pharmaceuticals from other countries into Indonesia. A number of companies continue to report trademark counterfeiting and infringement involving a wide range of products, including IT products, clothing and soft drinks. In July 2003, Indonesia's new copyright law came into effect. This law, first adopted in July 2002, addresses some concerns about Indonesia's compliance with its TRIPS obligations. But Indonesia still needs effective optical disc regulations that include a strong licensing requirement, sentencing guidelines that provide a strong deterrent, and other improvements. The United States will continue to use our bilateral TIFA to work with Indonesia to take the additional measures necessary to implement the IPR Work Plan submitted by the United States in May 2002.

## **KOREA**

Korea was elevated from the Special 301 Watch List to the Priority Watch List in January 2004 as the result of an out-of-cycle review conducted in late 2003. Korea has taken several positive steps over the last year, such as granting police authority to the Standing Inspection Team responsible for investigating software piracy; increasing efforts to report cases of infringement to U.S. right holders; and stepping up efforts to combat piracy on university campuses. In addition, the U.S. Government has been encouraged by the Korean Government's commitment to redraft regulations to clearly authorize the Korea Media Rating Board to identify and stop the fraudulent rating of videos, DVDs, and video games. Accordingly, we are optimistic that this legal loophole will be finally and permanently closed in the near future. The U.S. Government is also greatly encouraged by recent statements by President Roh recognizing the importance of protection of intellectual property and his instruction to the relevant ministries to devise ways to improve Korea's system of IPR enforcement. We hope that this new effort will produce tangible systemic improvements which will, in turn, reduce piracy in Korea.

Despite such progress, the U.S. Government remains seriously concerned that modern copyright protection continues to be lacking in important areas. Key among these is Korea's failure to adequately update its laws to protect sound recordings against digital piracy. Statements by the Korean Government indicating an unwillingness to provide national treatment to U.S. sound recording producers are also a source of concern, and further exacerbate this problem. As a result, online music piracy has continued to grow, causing serious economic damage to U.S. companies.

Other important flaws in Korea's legal regime for the protection of IPRs relate to temporary copies, technological protection measures, Internet Service Providers liability, reciprocity provisions regarding

database protection, *ex parte* relief, the lack of full retroactive protection for pre-existing copyrighted works, and copyright term extension. In addition, serious concerns have arisen over continuing book piracy in universities, street vendor sales of illegally copied DVDs, counterfeiting of consumer products, protection of pharmaceutical patents, and lack of coordination between Korean health and IPR authorities on pharmaceutical marketing approvals. Addressing these issues will continue to be a priority in bilateral discussions, including the U.S.-Korea Quarterly Trade Meetings.

## **KUWAIT**

Kuwait has been elevated to the Priority Watch List this year due to its failure to address serious and rampant copyright infringement and failure to amend its copyright law. Furthermore, Kuwait has failed to implement the 2002 work plan that outlined the steps it would take to increase IPR enforcement. In fact, in 2003, enforcement efforts remained insufficient and penalties for infringement remained inadequate to deter offenders. Kuwait continues to have the worst retail optical disc piracy rate in the region as well as problems with corporate end-user piracy, hard-disc loading piracy, and cable 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 and amending its copyright and other intellectual property law to correct its deficiencies. Kuwait Customs created a special IPR unit in April 2004 and began taking some enforcement actions. This is a positive sign but measures to combat infringement need to continue 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. These measures include a crackdown on illegal cable operators, a large-scale raid on pirated DVDs, movement toward full legalization of government software, and increased *ex officio* inspections along the borders. In addition, the Lebanese Government in April issued new requirements for registration of pharmaceutical products that, if implemented, should help prevent the registration of unauthorized copies of patented U.S. pharmaceuticals. It is too early, however, to evaluate the effectiveness of these measures. At the present time, Lebanon continues to face problems in providing adequate and effective protection of intellectual property rights. Problems persist with the widespread availability of pirated optical discs and rampant cable piracy. Registration of copycat pharmaceuticals has remained a serious issue, and ambiguous and unenforceable data exclusivity provisions remain causes for concern. Counterfeiting of trademarked goods including pharmaceutical products continues with little effort at deterrence. Furthermore, the judiciary remains slow and inefficient, and until recently there has been a general lack of sustained will in the government to improve IPR enforcement. Lebanon has also not yet joined the latest text of the Berne Convention or ratified the WIPO Copyright Treaty or the WIPO Performances and Phonograms Treaty. We urge the Lebanese Government to continue its efforts to address these problems and to ratify the WIPO Internet Treaties. The Lebanese Government's recent steps constitute its most serious efforts in some time to strengthen IPR protection. The United States will closely monitor these efforts in hopes that they will continue to the benefit of Lebanon's economy and our bilateral trade relationship.

## **PAKISTAN**

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. In 2003, Pakistan remained the

fourth largest source of counterfeit and piratical goods seized by the U.S. Customs and Border Protection. The vast majority of these goods were either apparel and pharmaceuticals with counterfeit trademarks or, optical media products. We recognize that Pakistan has taken some initial steps to address these problems, however, we are disappointed that Pakistan has taken minimal action to address these serious and long-standing concerns. The Government of Pakistan must conduct immediate, vigorous and sustained enforcement against the plants involved in piracy and counterfeiting. Additional concerns include lack of protection against the unfair commercial use of data submitted for marketing approval of pharmaceutical products, widespread trademark counterfeiting and copyright piracy beyond optical media (e.g., book piracy), and lax enforcement overall. The United States also remains concerned over a 2002 ordinance that seriously undermined improvements Pakistan made to its patent law in 2000. We do note that some positive developments were made in the past year including the issuance of new trademark regulations, Cabinet approval of legislation for creation of the Pakistan Intellectual Property Rights Organization (PIPPO) and formation of an IPR Advisory Group involving the private sector. However, despite these developments, the overall piracy and counterfeiting problems are worsening rather than improving. As a result, we are elevating Pakistan to the Priority Watch List. The United States urges Pakistan to intensify its IPR protection and enforcement efforts, including finding effective means to address the issues highlighted in the "IPR Roadmap" presented to Pakistan in July 2003. Further, we hope for expeditious passage by Parliament and the devotion of meaningful funding and resources for PIPPO. We will use the future Trade and Investment Framework Agreement discussions to continue pressing for improvements to address our IP-related concerns.

## **REPUBLIC OF THE PHILIPPINES**

Serious concerns remain regarding the lack of consistent, effective, and sustained IPR protection in the Philippines. U.S. distributors report high levels of pirated optical discs of cinematographic and musical works, computer games, business software, as well as widespread unauthorized transmissions of motion pictures and other programming on cable television systems. Trademark infringement in a variety of product lines also is widespread, with counterfeit or pirated merchandise openly available in both legitimate and illegitimate venues. The levels of illegal production and consumption of optical media remain consistently high. Although the estimated domestic demand for optical media is about seven million discs annually, industry and enforcement sources believe that there are at least 20 illegal production lines in the Philippines producing more than 70 million illegal DVDs, VCDs and CD-ROMs per year. We remain concerned over the Philippine Government's failure to implement data protection measures for innovative pharmaceutical and agricultural chemical products, and copyright provisions consistent with its obligations under the WIPO treaties. Many enforcement agencies suffer from a lack of resources while IPR issues remain a relatively low priority. Enforcement efforts such as raids and seizures often have only a temporary effect due to ineffective post-raid enforcement. Counterfeit goods from China, Malaysia, Hong Kong, Taiwan, and Thailand continue to enter the Philippines in large quantities. In response, the Bureau of Customs created a permanent IPR unit in September 2003 to investigate all shipments of counterfeit and pirated goods. Domestic enforcement suffers from lack of training and interagency coordination, which hinder raids, and there is a growing backlog of cases in the judicial system. The signing of the Optical Media Law in 2004 was a welcome step toward better protection of IP, and is intended to regulate the import, export and production of optical discs, including the tools and materials involved in the replication of optical discs. Full implementation of this law, including prosecution of IPR violators, is critical. Implementing regulations and the transformation of the Videogram Regulatory Board into the Optical Media Board have yet to be completed and will be a key factor in the effectiveness of the new law. The United States appreciates the Government of Philippines' efforts to address these concerns, and will continue to use the bilateral TIFA to address specific elements included in the IPR Action Plan concerning judicial, legislative and enforcement issues.

## **RUSSIA**

Certain aspects of Russia's IPR regime, including its copyright law and enforcement measures, are deficient and appear to be inconsistent with the 1992 U.S.-Russian Federation Trade Agreement (Bilateral Trade Agreement) and below the standards set in the TRIPS Agreement. While Russia recognizes that it must revise its IPR laws and enforcement measures to meet TRIPS requirements, key legislation is still pending. Russia has amended its laws on trademark, appellations of origins, patents, designs for integrated circuits, plant varieties, computer software, and databases. However, Russia's Copyright Law still does not provide protection for pre-existing works and sound recordings, although on April 21, 2004, the State Duma adopted, in a second reading, a set of amendments to the Russian Copyright Law that would, among other things, provide protection for pre-existing works and sound recordings. The Russian Government is working to enact amendments to its laws on protection of undisclosed information, in particular protection for undisclosed test data submitted to obtain marketing approval for pharmaceuticals and agricultural chemicals. Serious concerns also remain about Russia's reciprocity-based system for protection of geographical indications. Russia also needs to give its courts the authority in criminal cases to order forfeiture and destruction of machinery and materials used to make pirated and counterfeit products.

Border enforcement in Russia is particularly weak. Unauthorized production and export of pirated optical media products has become a significant problem, with the number and capacity of optical media facilities rising dramatically. U.S. industry believes that many of 32 optical disc facilities are producing illegal optical discs. Industry estimates losses of over \$1 billion annually as a result of this illegal activity. In addition, trademark counterfeiting remains significant and widespread, resulting in substantial losses for U.S. industry. We urge Russia to take immediate and effective steps to shut down illegal optical media plants, strengthen border enforcement, combat piracy and counterfeiting, and address deficiencies in its IPR laws. We will continue to monitor Russia's progress in these areas, including through the ongoing GSP review that was initiated by USTR in 2001.

## **TAIWAN**

Taiwan extended its 2002 "Action Year for IPR Protection" until 2005 and has moved to strengthen enforcement, particularly against pirated optical media. The United States commends the Taiwan authorities and in particular, its enforcement authorities, for increasing the frequency and effectiveness of raids against night markets and inspections of optical media factories, which have significantly reduced the number of pirated optical media products for retail sale. These are important and praiseworthy steps. However, the IP piracy community in Taiwan appears to have adjusted to increased pressure from authorities in ways that maintain business losses due to IPR infringement at unacceptably high levels. For example, production appears to be shifting from large optical media plants to small, custom optical media burning operations. There is evidence that infringers are using non-traditional retail channels, including catalogue sales to anonymous customers for home delivery and marketing pirated products over the Internet. Serious concerns also remain over counterfeiting and border enforcement. U.S. companies report that trade in counterfeit goods continues, including increased reports of counterfeit pharmaceutical products. The United States hopes that successful implementation of recently approved laws to increase penalties for the production and importation of counterfeit pharmaceuticals will lead to the elimination of this public health threat.

Taiwan needs to make the necessary changes to its relevant laws to prevent unfair commercial use of pharmaceutical and agricultural chemical test data and to strengthen its copyright law. Although Taiwan

amended its copyright law in June 2003, several provisions remain deficient. As recently as February 2004, Taiwan's Intellectual Property Office promised to work with legislators to seek further improvements to the copyright law, but improvements have not been enacted. The United States appreciates the efforts and steps that Taiwan has taken to strengthen its IP situation, and will continue to work with Taiwan officials on legislation and to achieve measurably improved enforcement results; including, if necessary, through higher-level engagement between USTR and Taiwan authorities. USTR has decided to conduct an out-of-cycle review in the fall to evaluate Taiwan's progress in achieving these objectives.

## **TURKEY**

Long-standing concerns over the lack protection for confidential test data were noted in the 2003 Special 301 Report. Unfortunately, Turkey has not implemented data exclusivity. The Turkish Government has indicated that it may soon announce implementation of this protection, however, actual implementation may be delayed – possibly until 2007. Under TRIPS, Turkey was obligated to have this protection in place as of 2000. Due to this continued and now possibly extended delay in implementation of data exclusivity, lack of interim protection for pharmaceuticals in the research and development “pipeline,” and with other serious concerns outlined below, Turkey has been elevated to the Priority Watch List. With regard to piracy, book piracy is the chief problem in Turkey, while piracy of optical media, mainly in the form of “burned” CD-Rs, has proliferated. IPR enforcement is also impeded by the judicial system. Although Turkey's 2001 copyright law improved the legal regime by providing deterrent penalties for copyright infringement, the courts fail to impose deterrent penalties against pirates. Amendments to the law in early 2004 banned street sales and allow for *ex officio* enforcement actions, which should provide additional tools to the government, but also lowered criminal penalties. In addition, counterfeiting, especially in apparel and designer brands, continues with little deterrence by the court system. The United States urges the Government of Turkey to enact data exclusivity for pharmaceuticals immediately, and to take more aggressive domestic and border enforcement actions such as criminal convictions and deterrent penalties to decrease counterfeiting and piracy

## **WATCH LIST**

### **AZERBAIJAN**

Azerbaijan has yet to fully implement the 1995 U.S.-Azerbaijan Trade Agreement and address deficiencies in its IPR laws. For example, copyright law in Azerbaijan does not explicitly provide for the protection of pre-existing works or sound recordings. The Criminal Code and Customs Code do not appear to provide for *ex officio* authority to commence criminal copyright cases and suspend the release of suspected infringing material at the border, and there is no explicit provision for civil *ex parte* search procedures. As a result of these inadequacies, IPR enforcement in Azerbaijan remains weak and ineffective. Furthermore, while Azerbaijani law does provide criminal penalties for IPR violations, U.S. copyright industries report that there have been no convictions for copyright infringement and that damage awards are difficult to obtain. We look to Azerbaijan to meet its obligations under the 1995 U.S.-Azerbaijan Trade Agreement and to improve its enforcement efforts by providing for *ex officio* raids and seizures as well as civil *ex parte* searches.

### **BELARUS**

Belarus must take several steps to fulfill its intellectual property commitments under the 1993 U.S.-Belarus Trade Agreement and to address other deficiencies in its IPR regime. With respect to its

copyright laws, Belarus has not provided 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 Copyright Treaty and the WIPO Performances and Phonograms Treaty. Enforcement of intellectual property laws in Belarus also remains weak and ineffective. Piracy levels remain high and the potential for increased piracy remains a concern due to the migration of optical media production facilities from neighboring countries. While Belarus has amended its Criminal Code to provide for deterrent penalties for IPR violations, there are still no provisions authorizing *ex officio* raids and seizures. Furthermore, Belarus' Civil Code does not provide for *ex parte* searches. We are also concerned that the Armita optical media plant case has not progressed beyond the initiation of a criminal investigation and that no criminal penalties or deterrent sentences have resulted. We encourage Belarus to aggressively enforce its IPR laws and to take actions to deter future illegal operations. In addition, we urge Belarus to fulfill its obligations under the 1993 Bilateral Trade Agreement and will continue to monitor its progress.

## **BELIZE**

This is the first time Belize has been placed on the Watch List in the past fifteen years. While IPR legislation in Belize is generally in line with international standards, the Government of Belize has made only minimal efforts at enforcement. This has led to the availability of counterfeit goods across many sectors, especially in the pharmaceutical and tobacco sectors. Furthermore, there has been insufficient cooperation between rights holders and government entities and lackluster responses to concerns raised by such rights holders. Another concern is the lack of enforcement of IPR in the Corozal Commercial Free Zone, which has encouraged infringement and related activities, including criminal activities. We urge Belize to improve enforcement efforts by promoting increased cooperation in counterfeiting investigations and implementing enforcement actions in the Corozal Commercial Free Zone.

## **BOLIVIA**

Bolivia's existing legislation for IPR protection is deficient. Bolivia has failed to provide for *ex parte* civil search orders. In addition, damages are inadequate, enforcement efforts have been sporadic and largely ineffective, and border enforcement remains weak. While the 1992 Copyright Law recognizes copyright infringement as a public offense and the new Bolivian Criminal Procedures Code began to provide for the criminal prosecution of IPR violations, enforcement by Bolivian Courts has been disappointing. Unfortunately, no progress has been made on amending the copyright law to bring it up to international standards. Furthermore, it appears that the Bolivian government agencies use unlicensed software. Piracy rates for videos, sound recordings, and software remain among the highest in Latin America, according to industry sources. Despite these serious deficiencies in enforcement, the Mesa Administration has publicly committed itself to transparency and has demonstrated at multiple levels a desire to work with the United States on institutionalization, combating corruption, and increasing the efficiency of the Bolivian Government. We welcome this commitment and urge the Bolivian Government to continue in its efforts to improve enforcement.

## **BULGARIA**

Bulgaria is being placed on the Watch List for the first time in five years following its inclusion on the Watch List and Priority Watch List from 1996-1999. After a dramatic decline in domestic production and export of pirated optical disc media in the late 1990's, there has been a steady resurgence of piracy, mainly in the sale of pirated optical disc media, in Bulgaria over the past few years. Pirated optical discs, mass imported finished discs, and illegally burned CD-Rs are prevalent in the domestic market. Poor

enforcement, including ineffective prosecutions, minimal judicial sentences, shortcomings in current and draft legislation, and lax border measures have contributed to this resurgence. Further amendments to close loopholes are still needed to fix the pending optical disc legislation. In addition, production and smuggling of counterfeiting of U.S. distilled spirits has grown at an alarming rate. Large public amusement centers use images of copyrighted cartoon characters. The Government of Bulgaria should take the necessary administrative actions to stop optical disc piracy and the counterfeiting of spirits and other goods. We commend Bulgaria for providing protection for confidential test data in its new drug law and for its commitment to have government ministries purchase and use only licensed business software. However, we remain concerned over the growing rate of copyright piracy and spirits counterfeiting and will continue to monitor Bulgaria's progress on effectively combating these illegal activities.

## CANADA

Canada has again been placed on the Special 301 Watch List. After making significant progress in improving its IPR regime in 2001 and 2002, Canada made little headway in addressing long-standing intellectual property issues related to copyright and patent reform such as ratification of the WIPO Internet treaties, and implementation of legislation on patenting of higher life forms. Progress has stalled on resolving the outstanding issue of national treatment of U.S. artists in the distribution of proceeds from Canada's private copying levy and its "neighboring rights" regime. Systemic inadequacies in Canadian administrative and judicial procedures continue to allow the early and often infringing entry of generic versions of patented medicines into the marketplace. Enforcement against IP infringement improved through a concerted government and industry effort to address radio signal theft, but these renewed efforts did not carry over into other areas of counterfeiting and piracy. In fact, a recent Canadian court decision has found peer-to-peer file sharing to be legal under the Canadian copyright law, a position that underscores the need for Canada to join nearly all other developed economies in implementation of the WIPO Internet treaties. Canada's border measures continue to be a serious concern for IP owners, who consider Canada's border enforcement measures to be inconsistent with its TRIPS obligations. The United States urges Canada to take effective measures to strengthen border enforcement, including the enactment of legislation that would allow Canada's customs officials to conduct *ex officio* searches of incoming and outgoing products suspected to be pirate or counterfeit.

## CHILE

The U.S.-Chile Free Trade Agreement (FTA) entered into force on January 1, 2004. The intellectual property chapter of the FTA provides high levels of protection appropriate for the digital age, including non-discriminatory treatment for U.S. software, music, text, and motion pictures. Protections for U.S. patents, trademarks, and undisclosed information obligate Chile to conform its IP laws and enforcement practices to advanced standards. The FTA includes important protections for Chilean writers, singers, and software developers, specifically ensuring that they will continue to reap the rewards of their creativity in the digital realm. In late 2003, two sets of amendments were made to the copyright law to implement TRIPS and the FTA. However, some substantive IPR deficiencies remain, and enforcement continues to be irregular. Copyright piracy is still quite high and indeed has increased slightly in recent years, as digital piracy becomes more prevalent. In addition, the United States was very disappointed with the registration of several pharmaceutical products that appear to infringe validly issued Chilean patents. We expect these issues to be resolved through Chile's implementation of the FTA and look forward to following Chile's progress in meeting its commitments. Upon full implementation of the U.S.-Chile Free Trade Agreement, we would expect to re-evaluate Chile's Special 301 status.

## **COLOMBIA**

During 2003, the Government of Colombia continued to demonstrate a commitment to strengthen IPR protection including passing a decree to provide data protection for agricultural chemicals, and increasing enforcement actions. However, high levels of piracy and lack of successful prosecutions for IPR infringement remain a problem. In addition, new IP protections such as Decree 2085, which protects confidential test data for pharmaceutical products remain subject to legal challenge, and enforcement needs to be more effective. Piracy levels in Colombia amount to three-quarters of the market for recorded music and motion pictures, and half of the market for business software; the publishing industry continues to suffer from piracy, especially photocopying piracy. Piracy of music CDs is on the increase, threatening to erode legitimate markets altogether, mostly due to local, cottage-shop CD-R duplication. The recent growth of optical disc piracy also threatens the new, legitimate DVD market. 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 penalties. Enforcement of trademark legislation in Colombia is showing some signs of progress, but contraband and counterfeiting are widespread and need to be stemmed by the Government of Colombia. The United States urges Colombia to ensure that its criminal, administrative, civil and border enforcement procedures meet its bilateral and multilateral intellectual property enforcement obligations and are effectively implemented.

## **COSTA RICA**

In January 2004, Costa Rica joined the Central American Free Trade Agreement, a step that will considerably upgrade the level of protection in Costa Rica's intellectual property regime. However, Costa Rica still faces IPR enforcement problems and, as such, shall remain on the Watch List. While the United States notes Costa Rica's efforts to ensure that local legislation conforms with the TRIPS Agreement, Costa Rica still needs to improve its criminal and civil systems of intellectual property enforcement, including establishing a specialized intellectual property prosecutor and by increasing resources to bolster enforcement efforts in the Ministry of Public Safety's Intellectual Property office. Furthermore, the Government of Costa Rica must make significant modifications and clarifications in the area of data protection as the CAFTA commitments come into effect. Also, the Government of Costa Rica must improve protection of new plant varieties and provide for stronger penalties for infringement. We encourage the Government of Costa Rica to take action in 2004 to improve the shortcomings in its criminal and civil systems of intellectual property enforcement by assigning priority and resources to these areas and to continue its work in ensuring that its local legislation conforms with CAFTA obligations.

## **CROATIA**

In February 2004, the Croatian Government ratified the 1998 U.S.-Croatia MOU Concerning Intellectual Property Rights. Croatia currently is drafting implementing regulations that will bring the MOU into force. While the ratification of the MOU is a positive step in improving IPR protection in Croatia, problems still persist. Croatia remains on the Watch List due to concerns with its patent regime, specifically its failure to protect confidential data submitted for marketing authorization as required by TRIPS, lack of coordination between the patent and health authorities to prevent patent infringement by the grant of marketing approval for copycat pharmaceuticals, and failure to provide expeditious and timely judicial remedies to parties seeking to stop infringing activities. Furthermore, companies seeking to register pharmaceutical products with the Ministry of Health encounter a lengthy registration period. We will continue to monitor Croatia's progress in fulfilling its MOU obligations in the near term, including its prompt implementation of new regulations for data protection. We look to Croatia to



provide adequate data protection, establish linkage for pharmaceutical products and to improve the registration process for pharmaceuticals, including by reducing the lengthy registration period.

## **DOMINICAN REPUBLIC**

In March 2004, the Dominican Republic concluded an FTA with the United States that will require the Dominican Republic to upgrade considerably the level of intellectual property protection in the Dominican Republic. However, concerns still remain regarding the protection and enforcement of intellectual property, particularly with respect to copyright piracy and patent protection. As such, the Dominican Republic shall remain on the Watch List. We remain concerned by the levels of copyright piracy in the Dominican Republic. While the Telecommunications Authority (Indotel) and the Copyright Office (ONDA) have taken some positive steps to enforce intellectual property, such actions have failed to deter infringements. A key problem has been the delays in obtaining judicial remedies, particularly criminal remedies, against violators. In addition, U.S. concerns regarding the patent provisions of the Industrial Property Law and the subsequent Presidential decrees remain. These concerns include, but are not limited to, issues regarding the issuance of compulsory licenses, subject matter eligibility for patents, and data exclusivity. We encourage the Government of the Dominican Republic to take measures to address these concerns as soon as possible. Furthermore, we look forward to the increased reporting and improved enforcement from the Government of the Dominican Republic to effectively address broadcast piracy and deter other copyright infringements, and its efforts to ensure an expeditious resolution of pending judicial cases. Finally, we urge the Dominican Republic to be vigilant in submitting legislation, enhancing enforcement, providing training, and making other necessary preparations to meet its FTA obligations.

## **ECUADOR**

Ecuador has shown little progress in improving IPR protection over the last year, and although it has a generally adequate IPR law, enforcement of the law remains a significant problem. Lack of effective protection for innovative pharmaceutical products is a serious concern. Ecuador does not provide protection of confidential test data, and the number of copy products granted marketing approval by the health authority continues to increase, due to the lack of any linkage system between the health and patent agencies. The United States urges the Government of Ecuador to protect confidential data from unfair commercial use and to facilitate an effective linkage system between its health and patent agencies. Enforcement of copyrights also remains a significant problem, especially with respect to sound recordings, computer software, and motion pictures, as does enforcement of trademark rights. As a result, there continues to be an active local trade in pirated audio and video recordings, computer software, and counterfeit brand name apparel. Music piracy is rampant in the streets of key cities, yet the local authorities appear to have made no efforts to prevent the sale of pirated music, nor have they investigated the duplication and distribution sources for these products. The Ecuadorian Government has yet to establish the specialized intellectual property courts required by the 1998 IPR law. Even though Ecuador's current substantive copyright legislation appears generally in line with its international obligations, the performance of Ecuador's judiciary remains deficient, in that the courts appear unwilling to enforce the law. The United States urges Ecuador to strengthen enforcement of IPR and will closely monitor Ecuador's efforts to address IP-related concerns.

## **GUATEMALA**

The United States commends Guatemala for implementing data protection last year for pharmaceutical and agricultural chemical products, which is in line with international standards. However, legislation

was introduced in April 2004 to revoke data exclusivity. If revocation were to occur, this would be a major step backwards in terms of fulfilling the TRIPS obligation to protect confidential test data, as well as one of the key intellectual property obligations in the recently concluded CAFTA. The United States urges Guatemala to maintain its current data protection regime and not roll back the progress it has achieved in providing adequate and effective IP protection for innovative pharmaceutical and agricultural chemical products. The United States will monitor this situation very closely.

## **HUNGARY**

In recognition of the ministerial decree providing for protection of confidential test data, Hungary was moved from Priority Watch List to Watch List last year. Nevertheless, we remain concerned about the fact that the decree provides retroactive protection for products that received first marketing authorization in the European Union or Hungary on or after April 12, 2001, rather than January 1, 2000, as required by TRIPS. Hungary needs to address this shortcoming in its data exclusivity law, improve coordination between the regulatory and patent authority to prevent patent infringement, and improve enforcement against intellectual property infringement by the Hungarian police, prosecutors and judiciary. We are encouraged by the advancements that Hungary has made in modernizing its copyright code, but poor enforcement of these laws has led to a high piracy rate of optical and auditory media. We urge the Hungarian Government to address the deficiencies in its data exclusivity law and continue to improve IPR enforcement efforts in all areas of intellectual property.

## **ISRAEL**

Israel is being maintained on the Watch List due to continuing serious U.S. concerns regarding its policies on data protection for proprietary test data and national treatment for U.S. rights holders in sound recordings. In 2003 Israel was moved from the Priority Watch List to the Watch List. Last year's move was based primarily on Israel's improvements in copyrights and trademark enforcement, as well as on senior-level assurances that OECD-level protection would be implemented for confidential test data submitted by innovator pharmaceutical and agricultural chemical producers, i.e., third parties would be prevented from relying on those data to obtain marketing approval ("data exclusivity"). Israel has also offered assurances in the past that it would take no action to affect its policy of national treatment copyright protection for U.S. producers of phonograms. Over the last year, Israel made further headway in copyright and trademark enforcement. We note that Israel recently joined the U.S. and ten other countries in the largest single law enforcement action ever undertaken against Internet piracy. While it remains to be seen whether Israeli prosecutions will result from this action, we view Israel's willingness to participate as a positive indication of Israel's willingness to improve criminal IPR enforcement. However, U.S. industry notes that the persistence of a significant level of piracy suggests that additional enforcement resources may be needed.

On the key issue of data exclusivity, Israel's actions have not met U.S. expectations. In April 2004, the Israeli Government developed a set of recommendations on data exclusivity that recognized for the first time the need to provide a minimum five-year period of protection for confidential test data for innovator firms in Israel. However, several serious shortcomings in the recommendations would severely compromise the data protection afforded by Israel, keeping it far short of OECD-level standards for data exclusivity. The Israeli Government has postponed further action on its data exclusivity recommendations and provided written assurance that it will engage with the United States to address U.S. concerns on data exclusivity. In addition, U.S. biotechnology firms suffer from a lack of adequate protection for their intellectual property, due to an onerous patent system that allows competitors to stall the grant of patent rights through open-ended, pre-grant opposition proceedings, as well as the lack of

data exclusivity. Regarding the national treatment issue with respect to copyrights in sound recordings, new provisions in Israel's draft copyright bill, coupled with Israel's failure to provide clarification on the future status of national treatment, run counter to Israel's previous assurances and have reinforced U.S. concerns that it could cease national treatment protection for U.S. rights holders. An out-of-cycle review will be held this summer to assess whether Israel has made sufficient progress in responding to U.S. concerns on confidential test data, in ensuring that Israel will continue to provide national treatment for U.S. rightholders in sound recordings, and to consider whether Israel's Special 301 status should be changed.

## **ITALY**

Despite the continued implementation of the 2000 Copyright Law and increased enforcement actions in 2003, piracy and counterfeiting rates in Italy remain among the highest in Western Europe. Widespread piracy continues in virtually all copyright-based sectors. Furthermore, although the Italian Society for Authors and Editors (SIAE) sticker requirement is waived for business software, a burdensome declaration procedure is necessary. While SIAE does not charge for declaration processing, companies must bear the internal administrative costs of following the procedure. In addition, U.S. industry reports that Italian government actions may adversely affect the prior practice of patent term extension for pharmaceuticals. Despite greater enforcement efforts by Italian law enforcement agencies and growing awareness of the economic and criminal implications of piracy and counterfeiting among some parts of the judicial system, IPR enforcement remains inadequate. We will continue to work with Italy to raise awareness regarding intellectual property issues and to improve IPR protection across all sectors. We urge the Italian Government to address the continued high piracy and counterfeiting rates, inadequate enforcement against these illegal activities by the judiciary, and curtailment of patent term extension for pharmaceuticals.

## **JAMAICA**

In January 2004, the Jamaican Parliament approved a bill to protect geographical indications. The Jamaican Government has also made commendable enforcement efforts over the past year. However, while Jamaica's trademark and copyright laws are generally in line with international standards, we remain concerned over the continued failure to enact the Patents and Designs Act to meet Jamaica's 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 has fulfilled a number of its IPR obligations under the 1992 U.S.-Kazakhstan Trade Agreement. However, some additional steps are required, particularly with respect to copyright protection and enforcement. Currently, Kazakhstan's copyright law does not explicitly incorporate protection for pre-existing works or sound recordings. Although searches and seizures increased in volume and thoroughness in 2003, enforcement of IPR in Kazakhstan remains weak, particularly criminal enforcement. Very few defendants are convicted, and those who are convicted receive only minimal penalties. As a result, piracy is still a major problem. Industry estimated that out of a total of 17.4 million cassettes and 5.8 million CDs that were sold in Kazakhstan in 2003, nearly three-quarters of cassettes and CDs (12.2 million cassettes and 4.1 million CDs) were pirated copies. While new Criminal Code provisions on IPR violations have been adopted, these provisions do not serve as an effective deterrent because the burden of proof in criminal cases is very high and the likelihood of conviction is

low. We urge the Government of Kazakhstan to consider strengthening these provisions. The Ministry of Justice has developed a plan directed at improving Kazakhstan's IPR regime that includes amending the Copyright Law to protect pre-existing works and sound recordings. The announced plan also aims to increase coordination among law enforcement agencies, public organizations and international organizations in order to fight piracy. The United States supports these efforts and will monitor the implementation and effectiveness of these proposed measures.

## **LATVIA**

Latvia gave high-level attention to IPR enforcement in 2003, but needs to provide more follow-through to IPR enforcement in order to improve the results of anti-piracy actions. Latvia continues to be a significant consumer of and transshipment point for pirated goods, especially from Russia. Piracy levels for motion pictures, records and music and entertainment software, in particular, remain high. Internet piracy is growing, particularly in the areas of music hosting, entertainment software and pirated video games. Although some progress has been made in the area of end-user business software piracy, unlicensed use of business software by government ministries remains a serious concern. The United States urges the Government of Latvia to implement its IPR action plan to both amend current laws and enact new laws that will provide stronger IPR protection and enforcement measures, such as civil *ex parte* searches. The United States also encourages Latvia to step up the number of police raids and customs *ex officio* seizures of pirate and counterfeit products, as well as prosecutions, to demonstrate its commitment to improving IPR protection and enforcement.

## **LITHUANIA**

Lithuania continues to make progress toward improving its legislative framework for protecting IPR and in combating software piracy. However, optical media piracy levels remain high and Lithuania is a key transshipment point in the Baltic region for pirated music CDs and audiocassettes, CD-ROMS, DVDs and video games. The United States urges Lithuania to implement optical media rules that effectively regulate the production, distribution, and export of optical media, and to provide for penalties for the illegal reproduction and distribution of sound recordings. In addition, Lithuania needs to implement its regulation on government use of legitimate software. Although the number of customs and police seizures of pirated and counterfeit products increased during the last year, enforcement efforts have not made significant headway in stemming these illegal activities. In particular, Lithuania should step up efforts to counter piracy at the retail level and stem the inflow of illegal products through Lithuania's eastern borders. The United States urges Lithuania to improve coordination among relevant government ministries, police, and customs officials to bolster IPR enforcement.

## **MALAYSIA**

During 2003, the Malaysian Government continued to make progress in curtailing domestic retail piracy while increasing enforcement activities against pirate optical disc production facilities. However, while Malaysia is publicly committed to strong IPR protection and enforcement, it remains the world's largest exporter of pirate entertainment software. Piracy rates remain high for optical media (especially entertainment software) and books, and the substantial export of illegal goods continues. Already high levels of software piracy are increasing due to lax enforcement against infringements that occur in Internet cafes. Trademark infringement continues to be a serious problem as well, affecting a wide range of industries and products. The slow progress of cases through the judicial system and few prosecutions make it difficult to combat counterfeiting and piracy. Counterfeit pharmaceutical products are a particular concern. In addition to strengthening patent protection for pharmaceutical products, Malaysia

also needs to protect confidential test data and pharmaceutical products by linking the marketing approval process to the patent registration process.

The United States remains seriously concerned over the continued high rate of production and export of pirated optical disc media, counterfeiting, lack of effective patent and data protection for pharmaceutical products, and lax enforcement. USTR will conduct an out-of-cycle review in the fall to evaluate Malaysia's progress in addressing these concerns.

## **MEXICO**

During the past year, Mexico took significant steps to improve IPR protection. The United States commends Mexico for resolving the "linkage" issue between the Mexican Institute of Industrial Property and the Ministry of Health by implementing in September 2003 a Presidential decree that requires applicants for safety and health registrations to show proof of a patent and proof that test data were obtained in a legitimate manner. In addition, Mexico enacted legislation classifying piracy as an organized crime, and has created a special IPR prosecutor within the Office of the Attorney General (PGR). However, lax enforcement at both the criminal and administrative level, and particularly against copyright piracy and trademark counterfeiting, remains a serious problem. Companies continue to report high rates of 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.

Copyright piracy remains a major problem in Mexico, with U.S. industry loss estimates growing each year and totaling \$712 million in 2003 – the second largest level of losses in the hemisphere. Pirated sound recordings and motion pictures are widely available throughout Mexico, crippling legitimate copyright-related businesses. Strong concerns remain over the amendments to Mexico's copyright law passed by the Congress in July 2003 and still in the process of implementation. These amendments failed to address the comprehensive reforms needed by Mexico to (1) effectively implement the obligations of the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty (Mexico is a member of both treaties); and (2) address deficiencies in Mexico's copyright law, such as the failure to provide for national treatment and inadequate provisions regarding the scope of exclusive rights. The United States urges Mexico to take the necessary steps to resolve the current deficiencies.

Enforcement against piracy and counterfeiting in Mexico remains weak, and the few raids by Mexican authorities 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 in all major cities; impose strong criminal penalties and destroy seized products, and increase the speed of administrative and judicial actions. In addition, the recently adopted organized crime law should be aggressively used to combat IPR infringements. We hope that previously held bilateral discussions on IPR can be revitalized to provide a constructive and productive forum to address and resolve these IPR concerns in an effective manner.

## **PERU**

There are continuing concerns with respect to Peru's IP regime over the lack of data protection, weakened patent protection, widespread piracy of copyrighted works, and lack of effective IPR enforcement. Both the United States Government and U.S. industry remain concerned with Peru's failure to provide a period of exclusivity for undisclosed test data submitted for marketing approval of pharmaceutical and

agricultural chemical products. Given the significant commercial damage caused by this failure, we urge Peru to issue a data protection decree as soon as possible. Due to Andean Community pressure, Peru continues to deny second-use patent protection for pharmaceuticals. On copyright protection, the Peruvian Government issued a software legalization decree in 2003 and took some steps toward improving enforcement, however, it has yet to approve the guidelines for software management. Piracy remains extremely high for sound recordings, textbooks, books, motion pictures, and software. Optical media piracy is on the rise in all sectors. According to industry sources, piracy of sound recordings has been on the increase in the last several years and is so severe now (98% of the market is estimated to be pirated) that it has virtually eliminated any legitimate market, causing the remaining legitimate sound recording businesses to shut down. While the government, 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, piracy continues to be a significant problem for copyright owners. Border enforcement measures also remain inadequate. 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 was elevated to the Priority Watch List in 2003 for three main reasons: 1) the general level of IPR protection was not improving, in part because of inadequate border controls and the rapid growth of domestic optical disc production capacity; 2) lack of political will to shut down the outdoor market in the Government-owned Warsaw Stadium, where pirated and counterfeit goods were abundant; and 3) Polish law did not provide adequate protection for pharmaceutical test data.

After being elevated to the Priority Watch List, the Polish Government demonstrated its willingness to address U.S. IP-related concerns, especially regarding copyright protection, and has made changes over the past year that have provided the foundation for long-term, sustained improvements. The United States recognizes the steps Poland took to initiate raids to combat high levels of piracy and counterfeiting at the Warsaw Stadium, strengthen its copyright law, pass legislation to regulate optical disc production, and accede to the WIPO Internet Treaties. In recognition of this progress, we are moving Poland from the Priority Watch List to the Watch List, and scheduling an out-of-cycle review in the fall to monitor and ensure Poland's continued efforts.

Given the firm position taken by the Polish Government in its August 2003 IPR enforcement action plan, we look forward to significantly increased efforts to combat piracy and counterfeiting activities at the Warsaw Stadium and elsewhere around the country. At the same time, serious problems, particularly in the areas of patent protection for innovative pharmaceuticals and mechanisms for reducing the supply of pirated and counterfeit goods, require urgent attention.

Measures to ensure effective protection for innovative pharmaceutical products from patent infringement need to be implemented. The commercial availability in Poland of generic versions of patent protected pharmaceutical products is a clear indication of the weak state of patent protection in Poland and its direct effect on U.S. company interests. In March 2004, the Polish Government indicated that it would undertake an initiative to institute formal cooperation between the Polish patent and drug registration offices, which could prevent future cases of improper registration and marketing approval. We welcome this positive signal and are awaiting concrete measures to facilitate linkage between the two relevant agencies and to strengthen the enforcement of existing patents.

While Polish customs enforcement has improved over time, pirated and counterfeit goods still cross

Poland's borders far too easily. For example, pirates import large amounts of unauthorized copies of optical media products, principally from Russia and Ukraine. Poland should tighten its border controls in response to its new EU obligations and continuing EU technical assistance, and we will be looking for demonstrable results this year. At the same time, we remain concerned about the potential for a sharp rise in locally-produced pirated optical discs. Optical disc production capacity in Poland is growing rapidly, overshooting local demand. Thus, we welcome changes to the Copyright Act that will impose new regulations on optical disc production and look forward to their swift and effective implementation.

Enforcement efforts are undermined by weaknesses in the judicial system that include the need to train judges and prosecutors on IPR issues, the need for better court information management systems, and the failure to impose penalties severe enough to deter IPR crime. We urge the Polish Government to expedite action on these points, which concern tens of thousands of judges, prosecutors, and judicial and prosecutorial facilities.

The United States will conduct an out-of-cycle review in the fall to ensure that Poland continues and even reinforces its efforts to strengthen IPR protection and enforcement and addresses remaining concerns. Results of the out-of-cycle review will be based on Poland's taking action in all the following areas: 1) strengthening anti-piracy and anti-counterfeiting measures at the Warsaw Stadium and continuing effective raids and prosecutions against piracy and counterfeiting activities across the country; 2) strengthening the protection of test data submitted by innovative pharmaceutical companies; 3) taking substantive steps to implement a coordination mechanism between the Health Ministry and the patent agency; 4) strengthening border enforcement; 5) signing into law and implementing new copyright amendments and optical disc regulations; and 6) taking concrete, effective steps to strengthen domestic enforcement of IPR. Other significant developments related to IPR will also be considered during the review.

## **ROMANIA**

IPR enforcement did not improve in Romania in 2003. High piracy levels continued across all sectors, optical disc piracy grew, and poor border enforcement led to a surge in imports of pirated material. The situation appeared to be further exacerbated by the lack of resources dedicated to enforcement. Prosecutions of IPR violators remain a rare event, and when cases are brought, deterrent penalties are rarely issued. In addition, Romania lacks legislation to protect confidential test data submitted to regulatory authorities for marketing approval. We look to Romania to strengthen enforcement efforts by increasing raids on illegal operations, improving and increasing prosecution of IPR violations, providing penalties that effectively deter criminal behavior, and improving border enforcement by providing government officials with *ex officio* authority to inspect and seize IPR infringing goods. We also look for the Romanian Government to enact a law to provide protection of confidential test data as required by TRIPS.

## **SAUDI ARABIA**

Although Saudi Arabia is working to improve its legal protections for intellectual property as part of its efforts to join the WTO, a number of issues remain to be resolved. Saudi Arabia's 2003 copyright law fails to provide adequate protection for sound recordings or *ex parte* civil search orders and fails to include deterrent penalties. Although Saudi officials report increased inspections, raids, and seizures, piracy rates for optical discs, books, and pay television remain high. Piracy of printed materials and the continued use of illegal software by the government further exacerbate the problem. Saudi officials report that enforcement of trademark laws has improved through spot checks and confiscation of counterfeit

goods. However, concerns remain about the failure to take action at the borders to seize imported pirated and counterfeit goods and the lack of transparency in Saudi Arabia's enforcement system overall. Saudi Arabia's patent registration system is seriously deficient, with a backlog of thousands of applications. While there have been no major incidences of patent infringement, a recent decision by the Saudi Board of Grievances threatens to undercut protection of intellectual property related to pharmaceutical products by failing to provide exclusive patent rights afforded by the registration of pharmaceutical inventions within a reasonable time. While we commend the progress that Saudi Arabia has made, we also urge continued efforts to improve IPR protection through continued sustained raids on copyright piracy sites, improved border enforcement, improved cooperation between government officials and rights holders, providing reports on enforcement actions and investigations to rights holders, and imposing deterrent sentences on IPR infringers.

## **SLOVAK REPUBLIC**

The Slovak Republic does not provide adequate protection for confidential pharmaceutical test data submitted to obtain marketing approval, and the United States remains concerned about this deficiency. The United States is also concerned about copyright piracy in the Slovak Republic. Although video piracy has declined, imports of pirated optical media, primarily from the Ukraine and Russia, have increased. We look to the Slovak Republic to implement TRIPS-consistent data protection and to increase and sustain government actions against piracy, particularly at the border.

## **TAJIKISTAN**

While Tajikistan has taken steps to fulfill its IPR obligations under the 1993 U.S.-Tajikistan Trade Agreement, Tajikistan's IPR regime has numerous deficiencies, particularly with respect to copyright protection. Specifically, Tajikistan has not joined the Geneva Phonograms Convention, does not provide IPR protection to foreign sound recordings, and does not explicitly protect pre-existing works or sound recordings under its copyright law. There are also problems with respect to the exclusive economic rights provided to authors under the Tajik Copyright Law. In addition, IPR enforcement in Tajikistan remains weak. Criminal penalties for IPR violations have not yet been adopted, nor is there proper *ex officio* authority to commence criminal cases. In addition, the Tajik Customs Code 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 through the consideration of draft legislation and regulations, and the development of initiatives to improve enforcement, but has achieved only limited progress. The United States continues to have serious concerns about the Thai Government's failure to effectively address the growth in optical media piracy, copyright and trademark infringement, counterfeiting, end user piracy, and cable and signal piracy. We are also concerned about Thailand's failure to date to enact implementing regulations for the Trade Secrets Act to provide effective data protection. We welcomed the stepped-up enforcement efforts that were initiated in the spring and again in the early fall of 2003 and the reduction in the visibility of retail piracy during the October APEC meeting, but are disappointed that these efforts were not sustained and that piracy levels remain high. Enforcement remains uncoordinated and sporadic, and the transfer of some responsibilities from police units to the newly formed Department of Special Investigations has caused some problems in the implementation of enforcement activities. The production, distribution, sale, and export or transshipment



of pirate and counterfeit products continues to be a serious concern. Counterfeit and pirated products sold in or exported from Thailand include optical discs video games, clothing/apparel, watches, leather goods, jewelry, lighters, auto parts, mobile phone accessories, batteries, and wine. Thailand also has one of the highest end-user piracy rates in Asia; and book piracy and broadcast piracy are growing problems. On the legislative side, Thailand enacted a law on geographical indications that became effective on April 28, 2004. However, the Thai government has failed to enact an optical disc law, and concerns remain over deficiencies in the current version of the optical disc bill and its draft implementing regulations. In addition, while the draft amendments to the Copyright Act include important improvements, some additional strengthening of the current draft is needed. These draft amendments have not yet been submitted to Parliament. 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 an FTA between our two governments.

## **TURKMENISTAN**

Turkmenistan has not satisfied all of its IPR obligations under the 1993 U.S.-Turkmenistan Trade Agreement. For example, Turkmenistan has not updated its copyright law to reflect international standards and has not signed the Berne Convention for the Protection of Literary and Artistic Works or the Geneva Phonograms Convention. Furthermore, Turkmenistan does not provide explicit protection for sound recordings or pre-existing works. IPR enforcement is inadequate. Turkmenistan has not adopted criminal penalties for IPR violations, and the Turkmen Customs Code does not provide *ex officio* authority to suspend the release of suspected infringing material at the border. The United States urges Turkmenistan to adopt the needed legal reforms and commence activities to strengthen IPR protection and enforcement.

## **URUGUAY**

The Uruguayan Government has yet to pass the implementing regulations for its 2002 copyright legislation to improve and strengthen Uruguayan copyright protection. IPR enforcement remains ineffective as evidenced by the Uruguayan Supreme Court pardoning of a known trademark infringer. Furthermore, the Uruguayan Government has not ratified the WIPO Performances and Phonograms Treaty and the WIPO Copyright Treaty. Uruguay also fails to provide adequate protection for confidential test data as required by TRIPS. We urge the Uruguayan Government to quickly pass implementing regulations for the new copyright legislation, ratify the WIPO Internet Treaties, address its deficiencies in enforcement against piracy and counterfeiting and provide protection for confidential test data.

## **UZBEKISTAN**

Uzbekistan has recently announced a plan to amend its IPR laws, improve its IPR enforcement, and join both the Berne Convention for the Protection of Literary and Artistic Works and the Geneva Phonograms Convention. Nevertheless, Uzbekistan still 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. IPR enforcement remains very weak, and weak criminal penalties for IPR violations do not serve as an effective deterrent. The United States urges Uzbekistan to remedy deficiencies in its IPR laws and to take measures to improve enforcement.

## **VENEZUELA**

The Venezuelan Government continues to show signs of decline in its commitment to IPR protection. In 2003, government policies regarding pharmaceuticals continue to raise concerns because they undermine patent and data protection for pharmaceutical products. The Venezuelan Government continues to grant marketing approval for domestic copies of patented pharmaceutical products and refuses to issue second use patents. Proposed changes to the new Industrial Property Law currently being debated in the National Assembly threaten to worsen the legal framework for protection of intellectual property. Levels of piracy and contraband have grown increasingly problematic while government efforts toward deterrence and prosecution of these illegal activities remain minimal. We urge the Venezuelan Government to improve IPR protection and to take action against the growing problems piracy and counterfeiting.

## **VIETNAM**

IPR violations remain a major problem in Vietnam, and enforcement continues to be ineffective despite improvements in laws and regulations. Judges in Vietnam have been reluctant to impose penalties or fines at a level sufficient to deter future infringements, and *ex officio* raids are sporadic at best. As a result, piracy remains rampant throughout Vietnam. Nearly 100 percent of sales of music CDs, VCDs and DVDs are pirated copies. Trademark violations are also prevalent, with unlicensed clothing and other items bearing famous trademarks available for purchase in small shops and stands throughout major cities. Patent protection remains inadequate, despite amendments to Vietnam's civil code extending the term of protection from 15 years to 20 years. Counterfeit pharmaceuticals are common in the marketplace. Market access barriers persist, especially with regard to products classified as "cultural products" that are subject to censorship and control regulations. Such barriers impede importation of legitimate products. However, Vietnam has made some efforts to strengthen IPR protection, including enacting stronger regulations in various sectors that require increased inspections and raids against suspected infringers. We will work with Vietnam to ensure full compliance with all of its obligations. We encourage Vietnam to continue to build upon its strong public commitment to IPR protection by translating Vietnam's obligations under the U.S.-Vietnam Bilateral Trade Agreement into strong laws and effective enforcement against piracy and counterfeiting.

## **Developments in Intellectual Property Protection**

**2003-2004**

### **2003**

#### **May**

- In Vietnam, a May 2, 2003 governmental decree on industrial property protection for layout design of integrated circuits established protection for original semiconductor integrated circuit designs.
- On May 6, 2003 Russia's Interministerial IPR Commission held its first meeting.
- In India, the May 2002 Patent Law amendment became effective in May 2003 although it still contains numerous categories of inventions that are not patentable. Data exclusivity protection is also necessary to improve India's patent regime.
- Togo became party to the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty on May 21, 2003.
- Ukraine's Supreme Rada adopted a law pertaining to IPR sanctions entitled "On Introducing Amendments to Certain Legislative Acts of Ukraine on Matters of Intellectual Property" on May 22, 2003.
- In May 2003, Colombia issued a new decree granting data protection for agricultural chemicals.
- In May 2003, the French Industry Minister published a 2003/2004 action plan, thereby creating a national anti-counterfeiting committee charged with strengthening criminal sanctions for IP crimes.
- Improved enforcement against piracy began in Malaysia in May 2003.

#### **June**

- China's State Administration of Industry and Commerce issued the Rules on the Determination and Protection of Well-Known Trademarks, the Measures on the Implementation of the Madrid Agreement on Trademark International Registration and the Measures on the Registration and Administration of Collective Trademarks and Certification Marks in April 2003, all of which became effective June 1, 2003.
- The Dominican Republic ratified the WIPO Performance and Phonograms Treaty on June 10, 2003 but has yet to deposit these documents with WIPO.
- Serbia and Montenegro joined the Convention for the Protection of Producers of Phonograms Against Unauthorized Duplication of Their Phonograms (the "Geneva Phonograms" Convention) on June 10, 2003.

- Togo joined the Convention for the Protection of Producers of Phonograms Against Unauthorized Duplication of Their Phonograms (the “Geneva Phonograms” Convention) on June 10, 2003.
- On June 12, 2003 Russia banned sales of audio and video products from street vendors in order to counter sales of pirated products.
- Serbia and Montenegro became party to the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty on June 13, 2003.
- Papua New Guinea became party to the Patent Cooperation Treaty (PCT) on June 14, 2003.
- On June 18, 2004, the Qatar Finance Ministry signed a software licensing agreement designed to ensure all government entities, including semi-privatized and state-owned corporations use licensed software.
- In June 2003, the Brazilian Congress launched a Commission of Parliamentary Inquiry (CPI) on piracy.
- Kazakhstan’s draft law on IPR was submitted to the Lower House of Parliament (Majilis) in June 2003, and will give the IPR Committee of the Ministry of Justice independent investigative authority.
- In June 2003, the Korean Ministry of Justice sent a directive to all regional prosecutor offices to work pro-actively in pursuing IPR infringement.
- Morocco's lower house passed a draft Copyright Law in June 2003.
- In June 2003, the New Zealand Government proposed amendments to the Copyright Act of 1994 to make it more consistent with the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty. The amendments are intended to ensure that the Copyright Act reflects developments in digital technologies and international developments in copyright.
- In June 2003, heightened anti-piracy enforcement efforts in Poland began to show an improvement in reducing the levels of copyright piracy for some industry sectors at the Warsaw Stadium.
- With the adoption of new copyright amendments in June 2003, which made piracy a public crime, the copyright industries have so far witnessed some welcome improvements in the overall enforcement climate in Taiwan.

## **July**

- Effective July 1, 2003, an amendment to the Austrian Copyright Act implemented the EU Directive on the Harmonization of Certain Aspects of Copyright and Related Rights in the Information Society and regulates copyrights of works on the internet, protection of computer programs and related damage compensation.
- In Korea, amendments to both the Copyright Act and Computer Programs Protection Act took effect on July 1, 2003. Among other things, these amendments and implementing regulations

provide the framework for a “notice and takedown” system to combat online copyright piracy. The Copyright Act amendments also strengthened the effectiveness of technological protection measures.

- Portugal’s new Industrial Property Code entered into force on July 1, 2003.
- In Vietnam, a July 1, 2003 circular jointly promulgated by the Ministry of Culture and Information and the Ministry of Finance on royalties established guidelines for royalty payment regimes and the use of royalty funds for some types of works.
- In Vietnam, a July 16, 2003 circular on implementation of the March 13, 2003 decree on advertising stipulated that advertisements adhere to the properties of the trademark as announced or registered with the relevant state management agency.
- On July 29, 2003, a new copyright law went into effect in Indonesia. The new law criminalizes violations, increases fines to UD 62,000, and extends prison terms up to seven years for dealers of pirated materials.
- Albania became party to the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (Madrid Protocol 1989) on July 30, 2003.
- Algeria adopted new laws related to copyrights and neighboring rights, trademarks, patent and integrated circuits in July 2003.
- Andorra adopted new laws related to copyrights and neighboring rights, trademarks, patents and integrated circuits in July 2003.
- In July 2003, Egypt issued implementing regulations for its June 2002 IPR law covering patents, trademarks, and botanical varieties (but not copyright).
- The special IPR section of Italy's administrative and civil courts began working in July 2003.
- Jordan passed Copyright Law Amendments in July 2003.
- In July 2003, President Lula signed a law that amended the criminal code in Brazil, increasing the minimum penalty for copyright violations (from one to two years’ imprisonment). The law also codified procedures to seize and destroy contraband and gave judges authority to dispose of seized goods to ensure they will not be used for commercial purposes.

## **August**

- On August 4, 2003, Bolivia ratified the Patent Cooperation Treaty (PCT).
- The Dominican Republic approved legislation to ratify the WIPO Copyright Treaty on August 26, 2003.
- Tunisia became party to the International Convention for the Protection of New Varieties of Plants (UPOV) on August 31, 2003.

- In August 2003, New Zealand's 2002 Trade Marks Act entered into force. The act creates new criminal offenses for counterfeiting trademarks and increases the penalties for pirating copyright goods.
- In August 2003, Poland adopted a national IPR strategy and objectives to combat piracy.
- In August 2003, Slovenia adopted regulations dealing with biotechnological inventions, supplementary protection for medicinal products and supplementary protection certificates for plan protection products.
- Since the Duarte Administration took office in August 2003, the Paraguayan Government has beefed up efforts to seize pirated CDs.

## **September**

- Egypt became party to the Patent Cooperation Treaty (PCT) on September 6, 2003.
- Following passage of a new trademark law in December 1999, India published implementing regulations to put the new trademark law into effect in September 2003. The new Trademark Act provides protection for service marks for the first time.
- On September 19, 2003, the Mexican Ministries of Health and Economy implemented a presidential decree requiring applicants for safety and health registrations to show proof of patent and proof that test data was obtained in a legitimate manner.
- In Brazil, a Congressional Caucus on piracy and tax evasion was formed in September 2003.
- China's National Copyright Administration issued the Measures on the Implementation of Administrative Penalties in Copyright Cases in July 2003 and became effective September 2003.
- In September 2003, the Greek Parliament ratified the WIPO Copyright Treaty and the WIPO Performance and Phonograms Treaty.
- In September 2003, Mexico's Office of the Attorney General's Special IPR Enforcement Unit became operational.
- In September 2003, Mexico's new compulsory licensing law on patents came into effect. The original draft of this bill was very broad, but the cooperation of the Mexican government was helpful in this effort and the results were positive for U.S. pharmaceutical investment interests.
- In September 2003, Saudi Arabia's updated Copyright Law was officially published. The new copyright law allows for stricter regulation of intellectual property and stronger deterrent penalties including jail terms and increased fines.
- In Saudi Arabia, a September 2003 Judicial Decision issued by the Board of Grievances increased the scope of icons that may receive trademark protection.
- In September 2003, Taiwan's Ministry of Justice conducted a successful raid against book piracy.

- Thailand's Parliament passed its Geographical Indications Act in September 2003.
- In September 2003, the United Arab Emirates' Ministry of Health (MOH) issued a circular granting exclusive marketing rights in the UAE for all innovative pharmaceutical products registered in other countries, strengthening IPR protection for pharmaceuticals.

## **October**

- Micronesia became party to the Berne Convention for the Protection of Literary and Artistic Works on October 7, 2003.
- On October 9, 2003, the Paraguayan Government issued Decree 527, creating the Specialized Technical Unit, which conducts anti-piracy investigations and works with prosecutors to seize pirated goods.
- In Vietnam, an October 17, 2003 circular on copyright protection for import and export commodities at the border jointly issued by the Ministry of Culture and Information and the Ministry of Finance provided guidelines for registration to protect most goods subject to copyright according to the law on customs and relevant regulations.
- The Korean National Assembly passed legislation in June 2003 granting police powers to the Ministry of Communication and Information's (MOIC) Standing Inspection Team. The law went into effect on October 18, 2003.
- Poland became party to the WIPO Performances and Phonograms Treaty on October 21, 2003.
- On October 22, 2003, New Zealand passed legislation prohibiting the parallel importation of films, videos and DVDs for the initial nine months after a film's international release.
- Botswana became party to the Patent Cooperation Treaty (PCT) on October 30, 2003.
- In October 2003, the Czech Republic amended its anti-counterfeiting law in order to implement EU Directives.
- In October 2003, the Korean Ministry of Information and Communication submitted a bill for an Internet address space management act to the National Assembly. The Bill is intended to enhance the legal foundation of the domain name dispute resolution committee and prohibit cyber-squatting.
- Starting in October 2003, there has been improvement in Taiwan's enforcement actions, including night raids and the inclusion of 200 new officers designated for IPR enforcement.

## **November**

- The United States became party to the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (Madrid Protocol 1989) on November 2, 2003.

- Cyprus became party to the WIPO Copyright Treaty on November 4, 2003.
- Cyprus 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 1989) on November 4, 2003.
- In Vietnam, a November 5, 2003 circular on the procedures to establish industrial property rights for patent and utility solutions streamlined internal regulations and processes with respect to the registration of patents and utility solutions and established procedures on granting, invalidating and canceling the title of protection of patents and utility solutions.
- In Vietnam, a November 5, 2003 circular on the procedures for establishing industrial property rights for industrial designs simplifies the procedures and requirements related to establishing intellectual property rights for industrial designs.
- On November 12, 2003, a new Sri Lankan intellectual property law came into force, governing copyrights and related rights, industrial designs, patents for inventions, trademarks and service marks, trade names, layout designs of integrated circuits, geographical indications, unfair competition and undisclosed information.
- On November 25, 2003, the Government of Spain modified its penal code to reinforce intellectual and industrial property protection. The revised penal code increases the punishments for crimes against IP infringements, especially for repeat offenders and will take effect on October 1, 2004.
- In November 2003, Chile passed two sets of copyright law amendments in order to implement its TRIPs obligations and its immediate obligations under the U.S. - Chile Free Trade Agreement.
- Hungary's 1997 Copyright Act was amended in November 2003, to ensure compliance with various EU directives; these amendments will enter into force on May 1, 2004.
- In November 2003, Kazakhstan issued a resolution directing enhanced cooperation on IPR enforcement between the Ministry of Justice, Procurator General, Ministry of Interior, Customs, and Financial Police.
- In November 2003, President Remengesau signed the Palau Island's Copyright Act. The act provides protection on a variety of artistic and intellectual properties for local and foreign artists.

## **December**

- Lithuania became party to the International Convention for the Protection of New Varieties of Plants (UPOV) on December 10, 2003.
- The U.S. and Paraguayan Governments negotiated a new IPR MOU in December 2003 replacing the 1998 MOU and focusing on areas that are still of concern, especially the lack of effective IPR enforcement.
- China's Supreme People's Court issued, on December 23, 2003, an amended "Interpretation of the applicable law and some other matters for hearing computer network copyright-related



disputes by the Supreme People's Court," which made minor changes in its previous "interpretations" to better correspond with China's 2001 copyright law amendments.

- Iran 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 1989) on December 25, 2003.
- On December 29, 2003, Korea's National Assembly passed legislation to give underlying authority to the Korea's Media Rating Board (KMRB) to close loopholes that had allowed video and DVD pirates to exploit Korea's film and video rating system.
- In December 2003, Argentina's Congress passed an amendment to the patent law to provide protection for products obtained from a process patent and to ensure that preliminary injunctions are available to intellectual property court proceedings.
- In December 2003, Brazil held its first National Anti-Piracy Day, during which several well-known Brazilian recording artists joined political leaders to witness the televised destruction of half a million pirated CDs.
- In December 2003, the Ghana Parliament passed five new IPR laws, including trademarks, patents, layout-designs (topographies) of integrated circuits, geographical indications and industrial designs.
- In December 2003, Luxembourg passed a law implementing the 1998 EU Design Directive.
- Panama law No. 1 of January 5, 2004 was passed in late December 2003. The law raised penalties for IPR infractions.

## **2004**

### **January**

- The U.S. - Chile Free Trade Agreement entered into force on January 1, 2004.
- A New Czech Republic Law on Consumer Taxes came into force on January 1, 2004, that bans the sale of alcohol and cigarettes in market stalls, and may help to curb the sale of illegal goods by reducing the profitability of such stands.
- The Hungarian Patent Act was modified by Act XXXIX of 2003 and entered into force on January 1, 2004. The Act was modified in order to bring Hungary in line with EU legislation and the European Patent Convention.
- Israel became party to the 1971 text of the Berne Convention for the Protection of Literary and Artistic Works on January 1, 2004.
- Namibia became party to the Patent Cooperation Treaty (PCT) on January 1, 2004.

- Ukraine's new Customs Code went into force on January 1, 2004, providing Customs Authorities the power to seize suspected illegal material at the border.
- Croatia became party to the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (Madrid Protocol 1989) on January 23, 2004.
- Jordan's deposited its instruments of accession for the WIPO Copyright Treaty on January 27, 2004 (entry into force on April 27, 2004).
- In January 2004, the Bangladesh Cabinet approved an amended copyright act, which is now waiting for Parliamentary approval.
- In January 2004, Bolivia's National Intellectual Property Service (SENAPI) signed an agreement with the Bolivian Customs Authority and the National Tax Administration in order to better combat the entrance of pirated materials and merchandise through Bolivian borders.
- In January 2004, the Jamaican Parliament approved a bill to protect Geographical Indications (GIs).
- In January 2004, an amendment to the Japanese copyright law took effect, extending the length of copyright protection from 50 to 70 years from the release date for movies and animated films, and simplifying the way damages are computed for copyright violations.
- In January 2004, revisions to Luxembourg's "Benelux" trademark system entered into force and created for the first time an administrative opposition procedure for trademarks.
- A new decree passed as part of Peru's tax reform in January 2004, requires importers of blank CDs to make value-added tax payments in advance, improving Peru's ability to track subsequent purchasers.

## **February**

- China's State Council issued the Amendments to the Patent Law Implementing Measures, effective February 1, 2003.
- The Former Yugoslav Republic of Macedonia (FYROM) became party to the WIPO Copyright Treaty on February 4, 2004.
- On February 10, 2004, Morocco's Parliament announced establishment of a permanent watchdog committee to promote public awareness about the threat of piracy.
- Philippine President Arroyo signed the Optical Media Bill into law on February 10, 2004. The law regulates the manufacture, mastering, replication, importation and exportation of optical media.
- Jordan's deposited its instruments of accession for the WIPO Performance and Phonograms Treaty on February 24, 2004 (entry into force on May 24, 2004).

- On February 25, 2004, the Mauritius Supreme Court upheld the temporary injunction against the producers and retailers of counterfeit apparel of a prominent U.S. apparel company. This has the effect of a permanent injunction against the named counterfeit producers and retailers.
- In February 2004, China recognized two U.S. companies' trademarks as well-known marks.
- A draft civil procedure code that includes civil ex parte search provisions passed the first reading in the Estonian parliament in February 2004.

### **March**

- China's State Council Regulations on Customs Protection of IPR became effective March 1, 2004. These regulations prohibit the import and export of IPR infringing goods and improve some aspects of customs procedures for seizing IPR Infringing goods.
- On March 2, 2004, the United States and Morocco reached final agreement on a Free Trade Agreement, whereby it agreed to high levels of patent and copyright protection as well as enforcement, including full implementation of accession to the WIPO "Internet" treaties.
- On March 3, 2004, the Croatian Parliament approved the U.S. - Croatia MOU on Intellectual Property Rights.
- On March 3, 2004, at the request of the United States Government, the Korean Ministry of Education sent a letter to nearly 200 four-year universities in Korea, instructing school authorities to take extra measures to prohibit book piracy and actively cooperate with related officials' efforts to strengthen IPR protection activities.
- Nicaragua became party to the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty on March 6, 2003.
- Saudi Arabia joined the Paris Convention for Protection of Industrial Property and the Berne Convention for Protection of Literary and Artistic Works effective March 11, 2004.
- Poland became party to the WIPO Copyright Treaty on March 23, 2004.
- On March 23, 2004 Ukraine's regulations defining procedures for the acquisition and use of software by government agencies came into effect.
- In March 2004, the United States and Bahrain negotiated the intellectual property language of the Free Trade Agreement, whereby Bahrain will agree to high levels of patent and copyright protection as well as enforcement, including full implementation of and accession to the WIPO "Internet" treaties.
- In March 2004, the Polish Sejm and the Senate adopted a legislative package, which included provisions regulating optical disc manufacturing and copyright law amendments necessary in order to comply fully with EU directives. The Sejm is expected to vote on the bill in early April.

- In March 2004, Turkey's Parliament passed a law to ban street sales of copyrighted materials, and to, among other things, establish *ex officio* authority to enforce copyrights.
- In March 2004, the Government of Mauritius subsequently brokered a settlement between the U.S. apparel company and several of the counterfeiters, whereby the latter would cease production of counterfeit merchandise and make a cash payment to the U.S. company. In return, the U.S. company agreed to allow existing stocks of counterfeit merchandise to be sold, under controlled circumstances, through mid-2004.

#### **April**

- The Government of Mauritius is finalizing implementing regulations for copyright legislation passed in 2003 and has shared the draft regulations with the above-cited company for review. The regulations are expected to be issued in Spring 2004.
- In April 2004, the Government of Pakistan issued trademark regulations that are consistent with its TRIPs obligations.

**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 2003-April 2004. The WPPT entered into force on May 20, 2002.

Guatemala	January 8, 2003
Nicaragua	March 6, 2003
Poland	October 21, 2003
Serbia and Montenegro	June 13, 2003
Togo	May 21, 2003

In addition, Jordan has deposited their instrument of accession and will become a party to the WPPT on May 24, 2004.

The following became parties to the World Intellectual Property Organization (WIPO) Copyright Treaty (WCT) during May 2003-April 2004. The WCT entered into effect on March 6, 2002.

Cyprus	November 4, 2003
Guatemala	February 4, 2003
Jordan	April 27, 2004
Nicaragua	March 6, 2003
Poland	March 23, 2004
Serbia and Montenegro	June 13, 2003
Togo	May 21, 2003