

PRIORITY WATCH LIST

ARGENTINA

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

BRAZIL

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

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

EGYPT

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

INDIA

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

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

INDONESIA

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

ISRAEL

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

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

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

KUWAIT

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

LEBANON

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

PAKISTAN

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

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

REPUBLIC OF THE PHILIPPINES

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

RUSSIA

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

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

TURKEY

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

VENEZUELA

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