

SECTION I. DEVELOPMENTS IN IPR PROTECTION AND ENFORCEMENT

Innovation and creativity are pillars of global economic development. Key to any nation's economic success is the ability to trade intellectual property – including the goods and services that flow from new ideas – in a rules-based system around the world. An important part of the mission of the Office of the United States Trade Representative is to ensure that U.S. creators and innovators benefit from adequate and effective protection and enforcement of their IPR in markets around the world.

IPR infringement causes significant financial losses for rightsholders and legitimate businesses around the world. In its most pernicious forms, it can also endanger the public. Counterfeiting of some products, such as car parts and medicines, poses a real risk to health and safety. Trade in counterfeit and pirated products often fuels organized criminal networks and hinders sustainable economic development in many countries.

Initiatives to Strengthen IPR Internationally

The United States has worked to promote adequate and effective protection and enforcement of IPR through a variety of mechanisms, including the following initiatives:

- **World Trade Organization (WTO):** The multilateral structure of WTO agreements provides opportunities for USTR to lead engagement with trading partners on IPR issues in several contexts, including accession processes for prospective members like Russia; the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS); and dispute settlement.
- **Bilateral and Regional Initiatives:** The United States is pleased to have worked together with many countries to strengthen IPR protection and enforcement through the provisions of bilateral and regional agreements, including free trade agreements (FTAs). In addition, Trade and Investment Framework Agreements (TIFAs) between the United States and several countries, including many in the Middle East and Asia, have facilitated discussions on enhancing IPR protection and enforcement.
- **Anti-Counterfeiting Trade Agreement (ACTA):** The goal of the ACTA initiative is to work with trading partners in favor of strong IPR enforcement to achieve an agreement that raises the international standard for the enforcement of IPR. On April 6, 2009, USTR and its ACTA partners released a detailed summary of the issues under negotiation.
- **Trade Preference Program Reviews:** USTR reviews IPR practices in connection with the implementation of trade preference programs such as the Generalized System of Preferences (GSP). USTR will continue to review IPR practices in Russia, Lebanon, and Uzbekistan under ongoing GSP reviews. As part of its bi-annual review of the operation of the Caribbean Basin Economic Recovery Act, USTR will review the IPR practices of beneficiaries, including The Bahamas, to assess compliance with the preference

program's eligibility criteria, which include the extent to which a country prohibits its nationals from broadcasting U.S. copyrighted materials without permission.

- **Asia-Pacific Economic Cooperation (APEC) forum:** The United States encourages APEC members – some of whom have significant IPR enforcement challenges – to put in place legal regimes and enforcement systems to better combat counterfeiting and piracy. In the past year, the United States led efforts to ensure effective implementation of previously agreed-upon initiatives on IPR protection and enforcement, including the APEC Anti-Counterfeiting and Piracy Initiative and the APEC Cooperation Initiative on Patent Acquisition Procedures. In 2008, APEC Leaders and Ministers underscored the importance of continuing and building upon this work in 2009 by addressing areas such as satellite and cable signal theft, and patent examination practices in the region. The United States will work with the other APEC economies on these efforts.
- **Expanded International Cooperation:** USTR, in coordination with other agencies, is looking forward to continuing engagement with trading partners in bilateral, regional, and multilateral fora to improve the global IPR environment. In addition to the work listed above, we anticipate engaging with our trading partners in initiatives such as the G-8, the U.S.-EU Summit, our trilateral cooperation with Canada and Mexico, the Organization for Economic Cooperation and Development (OECD), and other multilateral and regional fora.

Trends in Counterfeiting

Counterfeiting has evolved in recent years from a localized industry concentrated on copying high-end designer goods to a sophisticated global business involving the mass production and sale of a vast array of fake goods, including items such as counterfeit toothpaste, shampoos, razors, electronics, batteries, food and beverages, chemicals, sporting goods, automobile and airplane parts, medicines, and health care products.

Counterfeiting affects the profits of legitimate producers and impacts consumers whose lives and safety are at risk when they purchase fake goods. It also damages the economies of the countries in which it occurs by decreasing tax revenue and deterring investment. Counterfeiters generally pay no taxes or duties, and they often disregard basic standards for worker health and safety, and product quality and performance. Industry reports trends in counterfeiting including:

- A greater diversification in the types of goods that are being counterfeited, as well as the production of labels and components for these fake products. Exploiting free trade zones (FTZs), counterfeiters are establishing a global trade in these items, shipping them separately to FTZs to be assembled and distributed in another country.
- Piracy of copyrighted products in virtually all formats, as well as counterfeiting of trademarked goods, has grown rapidly because these criminal enterprises offer enormous profits and little risk. Counterfeiters and pirates require little up-front capital investment, and even if caught and charged with a crime, the penalties imposed in many countries are so low that they offer little or no deterrence.

Stronger and more effective criminal and border enforcement is required to stop the manufacture, import, export, transit, and distribution of pirated and counterfeit goods. Through bilateral consultations, FTAs, and international organizations, USTR is working to maximize the deterrent effects of remedies, including stronger penalties and requirements for the seizure and destruction of pirated and counterfeit goods, and the equipment used in their production.

The manufacture and distribution of counterfeit pharmaceuticals is a growing problem that poses special concerns for consumer health and safety. The United States notes its concern with the proliferation of the manufacture of counterfeit pharmaceuticals in Brazil, China, India, Indonesia, and Russia, and the sale and distribution of counterfeit pharmaceuticals in many countries. A significant contributing factor in this problem is the unauthorized use of bulk active pharmaceutical ingredients (APIs) to manufacture counterfeit pharmaceuticals. For instance, in China, domestic chemical manufacturers that produce APIs can avoid regulatory oversight by not declaring that the bulk chemical is intended for use in pharmaceutical products. While China has acknowledged that this loophole must be addressed and has committed to expanding its regulations to control bulk chemicals used as the underlying source of many counterfeit drugs, we continue to urge China to adopt policies that will in fact reduce the manufacture and distribution of unauthorized APIs.

Internet and Digital Piracy

The increased availability of broadband Internet connections around the world has made the Internet an extremely efficient vehicle for disseminating copyright-infringing products. Internet piracy is a significant concern in a number of trading partners, including Canada, China, Greece, Hungary, Korea, Poland, Romania, Russia, Spain, Taiwan, Ukraine, and Vietnam. Unauthorized retransmission of live sports telecasts over the Internet continues to be a problem in many countries, particularly in China. In addition, piracy using new technologies is an emerging problem internationally. For example, U.S. copyright industries report growing problems with piracy using cellular telephones, palm devices, flash drives, and other mobile technologies. In some countries these devices are being pre-loaded with illegal content before they are sold. In addition to piracy of music and films using these new technologies, piracy of ring tones, games, and scanned books also occurs. Countries with significant problems of piracy using these new technologies include China, India, Indonesia, Malaysia, and the Philippines. The United States will work with these governments to combat these increasing problems. The United States urges governments to ratify and implement the WIPO Internet Treaties, which provide for the tools necessary to protect copyrighted works in the digital environment.

Although Internet piracy is rapidly supplanting physical piracy in many markets around the world, production of and trade in pirated optical discs remains a major problem in many parts of the world. In recent years, some countries, such as Brazil, Pakistan, the Philippines, and Ukraine, have made progress toward implementing controls on optical media production. Other countries still need to adopt and implement legislation or improve existing measures to combat illegal optical disc production, including Bangladesh, China, India, Russia, and Thailand, which have not made sufficient progress in this area. The United States continues to urge its trading partners

who face illegal optical media production within their borders to pass effective legislation to counter this problem and aggressively enforce existing laws and regulations.

Government Use of Software

Under Executive Order 13103 issued in September 1998, United States Government agencies maintain procedures to ensure the authorized and legitimate use of business software. Pursuant to the same directive, USTR has undertaken an initiative to work with other governments, particularly in countries that are modernizing their software asset management systems or where concerns have been raised, to stop governmental use of illegal software. Considerable progress has been made under this initiative, leading to numerous countries and territories mandating that only authorized, legitimate software may be used by government ministries. Further work on this issue remains with certain countries such as Belarus, China, Peru, Saudi Arabia, and Ukraine. The United States looks forward to the adoption by these governments of effective and transparent procedures to ensure legitimate use of software.

Intellectual Property and Health Policy

As affirmed in the 2001 WTO Doha Declaration on the TRIPS Agreement and Public Health, the United States respects a country's right to protect public health, in particular, to promote access to medicines for all and supports the vital role of the patent system in promoting the development and creation of new and innovative lifesaving drugs.

Consistent with these views, the United States respects our trading partners' rights to grant compulsory licenses in a manner consistent with the provisions of the TRIPS Agreement, and encourages our trading partners to consider ways of addressing their public health challenges while maintaining stable intellectual property systems that promote investment, research, and innovation.

The United States is firmly of the view that international obligations such as those in the TRIPS Agreement have sufficient flexibility to allow countries to address the serious public health problems that they may face. We strongly support the TRIPS/health solution concluded in August 2003, in which members are permitted, in accordance with specified procedures, to issue compulsory licenses to export pharmaceutical products to countries that cannot produce drugs for themselves. The General Council adopted a Decision in December 2005 that incorporated this solution into an amendment to the TRIPS Agreement, and later that month the United States became the first WTO member to formally accept this amendment. The United States hopes to see at least two-thirds of the WTO membership accept this amendment by the December 31, 2009 deadline, at which point the amendment will go into effect for those members that accept it. The August 2003 waiver will remain in place and available until the amendment takes effect.

The United States will work to ensure that the provisions of our bilateral and regional trade agreements are consistent with these views, and do not impede the taking of measures necessary to protect public health. In addition, USTR will continue its close cooperation with the Department of Health and Human Services, which contributed to the negotiation of the recently adopted *Global Strategy on Public Health, Innovation and Intellectual Property* and the agreed

parts of its *Plan of Action* at the World Health Organization, to ensure that public health challenges are addressed and the patent system is supported as a mechanism to promote research and innovation.

Supporting Pharmaceutical Innovation

USTR has sought to eliminate market access barriers faced by U.S. pharmaceutical companies in many countries and to provide for both affordable health care today and support for the innovation that assures improved health care tomorrow. For example, this year's Special 301 Report highlights concerns regarding market access barriers affecting pharmaceuticals in Algeria and Indonesia.

Other types of measures have the potential to affect market access in this sector, even where a country's IPR regime is adequate. For example, price controls and regulatory and other barriers can discourage the development of new drugs. These barriers may include unreasonable regulatory approval delays, linkages between dispensing and prescribing, and reference pricing or other potentially unfair reimbursement policies. The criteria, rationale, and operation of such measures are often nontransparent, or not fully disclosed to patients or the pharmaceutical companies seeking to market their drugs.

The United States also is seeking to establish or continue dialogues with Organization for Economic Cooperation and Development (OECD) members and other developed economies to address concerns and encourage a common understanding on questions related to innovation in the pharmaceutical sector. For example, the United States-Korea Free Trade Agreement, once in force, would improve access to innovative products and ensure the transparent, predictable, and non-discriminatory pricing and reimbursement of innovative and generic pharmaceutical products, medical devices, and biologics. U.S. industry has expressed concerns regarding the policies of several industrialized trading partners, including Canada, France, Germany, Italy, Japan, New Zealand, and Taiwan, on issues related to innovation in the pharmaceutical sector and other aspects of health care goods and services.

With respect to Japan, pharmaceutical and medical device issues are an integral part of the bilateral regulatory reform discussions. While progress has been made, the United States continues to press for improved transparency, including by ensuring meaningful opportunities for interested stakeholders to provide input into important regulatory, reimbursement, and pricing matters, facilitating the introduction of innovative new pharmaceuticals and medical devices into Japan's market.

The United States remains concerned about Poland's enactment in 2006 of a regulation establishing wholesale and retail processes for drugs, which appears to reduce the official maximum wholesale and retail prices for imported drugs by 13 percent while generally leaving unchanged the prices for drugs of Polish origin. The U.S. pharmaceutical industry reports that this regulation has had a significant impact by reducing prices for numerous products manufactured outside Poland. Poland is in the process of drafting such implementing legislation. The United States shares the EC's concerns over this regulation and will continue to monitor the situation in Poland throughout the coming year.

The United States continues to urge China to add, on a regular basis, new drugs to its national formulary, which controls access to medicines for China. The United States also urges China to adopt regulatory and reimbursement policies for medical devices that support innovation and increase transparency and predictability in that market.

The United States shares policy goals and concerns related to health care with other industrialized countries, including challenges surrounding aging populations and rising health care costs. The United States also shares the objective of continued improvement in the health and quality of life of its citizens and delivering care in the most efficient and responsive way possible. The United States hopes these dialogues will help to address specific concerns related to price controls and regulatory and transparency issues, as well as to develop a constructive dialogue with these countries on health policy issues of mutual concern.

Implementation of the WTO TRIPS Agreement

The TRIPS Agreement requires all WTO members to provide certain minimum standards of IPR protection and enforcement, and was one of the most significant achievements of the Uruguay Round. The TRIPS Agreement is the first broadly-subscribed multilateral IPR agreement that is subject to mandatory dispute settlement provisions.

Developed country members were required to implement TRIPS fully as of January 1, 1996. Developing countries were given a transition period for many obligations until January 1, 2000, and in some cases, until January 1, 2005. Nevertheless, certain members are still in the process of finalizing implementing legislation and many are still engaged in establishing adequate IPR enforcement mechanisms.

The United States will continue to work with WTO members and expects further progress in the near term towards completing their TRIPS implementation process. However, in those instances in which additional progress is not achieved, the United States will consider other means of encouraging implementation, including the possibility of recourse to dispute settlement consultations.

Recognizing the particular challenges faced by least-developed countries, in 2005 the United States worked closely with them and other WTO members to extend the implementation date for these countries from January 2006 to July 2013. The least-developed country members in turn pledged to preserve the progress that some have already made toward TRIPS compliance. In addition, the least-developed country members have until 2016 to implement their TRIPS obligations for patent and data protection for pharmaceutical products, as proposed by the United States at the Doha Ministerial conference of the WTO. The United States looks forward to the successful completion of this transition.

The United States participates actively in the WTO TRIPS Council's scheduled reviews of WTO members' implementation of the TRIPS Agreement, and also uses the WTO's Trade Policy Review mechanism to pose questions and seek constructive engagement on issues related to TRIPS implementation. Additionally, the United States continues to work with other WTO

members, including the European Communities, Japan, and Switzerland, to encourage a discussion within the WTO TRIPS Council on implementation of the enforcement-related provisions of the TRIPS Agreement. The United States hopes that the TRIPS Council can generate a useful sharing of experiences related to IPR enforcement, in the interest of ensuring effective implementation of enforcement obligations.

WTO Dispute Settlement

The United States will continue pursuing the resolution of WTO-related disputes announced in previous Special 301 reviews and determinations. The most efficient and therefore preferred manner of resolving our concerns is through bilateral dialogue. Where these efforts are unsuccessful, the United States will consider utilizing the dispute settlement process.

In April 2007, the United States requested WTO dispute settlement consultations with China over deficiencies in China's legal regime for protecting and enforcing copyrights and trademarks on a wide range of products. After those consultations failed to resolve the matter, the United States requested the establishment of a WTO panel. A WTO panel was established to examine this matter on September 25, 2007.

On March 20, 2009, the WTO Dispute Settlement Body ("DSB") adopted a panel report ruling in favor of the United States that (1) China's denial of copyright protection to works that do not meet China's content review standards is impermissible under the TRIPS Agreement; and (2) China's customs rules cannot allow seized counterfeit goods to be publicly auctioned after only removing the infringing mark. With respect to the third claim concerning China's thresholds for criminal prosecution and conviction of counterfeiting and piracy, while the United States prevailed on the interpretation of the important legal standards in Article 61 of the TRIPS Agreement, including the finding that criminal enforcement measures must reflect and respond to the realities of the commercial marketplace, the panel found that it needed additional evidence before it could uphold the overall U.S. claim that China's criminal thresholds are too high. The United States looks forward to working with China to implement the Dispute Settlement Body's (DSB) recommendations and rulings in this dispute.

In addition, the United States requested WTO dispute settlement consultations with China concerning certain other Chinese measures affecting market access. These measures appear to be inconsistent with various WTO obligations of China. This consultation request focuses on a Chinese legal structure that denies foreign companies the right to import publications, movies, music, and videos, that severely impedes the efficient and effective distribution of publications, music, and videos within China, and that disadvantages imported publications, movies, and music *vis-à-vis* their domestic counterparts in their distribution. As the United States and China were unable to resolve this dispute in these consultations, the United States filed a request for the establishment of a WTO panel. A WTO panel was established to examine this matter on November 27, 2007, and was composed on March 27, 2008. The panel proceedings are currently underway.

Following the 1999 Special 301 review, the United States initiated dispute settlement consultations concerning the European Union's (EU) regulation on food-related geographical

indications (GIs), which appeared to discriminate against foreign products and persons – notably by requiring that EU trading partners adopt an “EU-style” system of GI protection – and appeared to provide insufficient protections to trademark owners. On April 20, 2005, the DSB adopted a panel report ruling in favor of the United States that the EU GI regulation is inconsistent with the EU’s obligations under the TRIPS Agreement and the General Agreement on Tariffs and Trade 1994. The DSB found that the EU’s GI regulation impermissibly discriminates against non-EU products and persons and that Europe could not, consistent with WTO rules, deny U.S. trademark owners their rights. The DSB ruled that, under the regulation, any exceptions to trademark rights for the use of registered GIs were narrow, and limited to the actual GI name as registered. On March 31, 2006, the EC published a revised GI Regulation that is intended to comply with the DSB recommendations and rulings. There remain some concerns, however, with respect to this revised GI Regulation, which the United States has asked the EC to address, and the United States intends to continue monitoring this situation.

Positive Developments

Several countries made significant positive progress on IPR protection and enforcement in 2008 and early 2009. For example:

- **Korea** – USTR is pleased to announce that Korea is being removed from the Special 301 Watch List in recognition of the significant improvements it has made during the past year, and the Korean Government’s policy direction of continuing to place a priority on improving its IPR regime. This marks the first time in the history of the report that Korea has not appeared on either the Watch List or the Priority Watch List. USTR will, however, continue to monitor closely the ongoing problem of Internet piracy in Korea, and will be prepared to consider returning Korea to the Watch List in the future if it does not respond effectively to this challenge through its implementation of newly enacted legislation and other steps.
- **Taiwan** – In January 2009, USTR announced the removal of Taiwan from the Watch List following an OCR. During this period of review, Taiwan established a Specialized IPR Court and made progress implementing the Ministry of Education Action Plan for Protecting IPR on School Campuses, and, in April 2009, Taiwan prosecutors initiated a significant prosecution involving a peer-to-peer (P2P) network under the 2007 amendments to Taiwan’s copyright law. On April 21, 2009, Taiwan’s Legislative Yuan enacted a new law to provide limitations on Internet Service Provider (ISP) liability if ISPs establish and follow certain procedures, including an expeditious notice-and-takedown regime.
- **China** – During the Beijing Olympics, the Chinese Government went to unprecedented lengths to launch a coordinated crackdown on the unauthorized retransmission of sporting events as well as online activities related to the Olympic Games. These efforts reportedly resulted in 453 online infringement cases, through which 192 sites were shut down, 173 sites were required to remove infringing content, 88 sites received administrative punishment, and infringing activities related to 10 sites were transferred

for criminal prosecution. This experience shows that when the Chinese Government chooses to exercise its political will to deal with an IPR problem, it can yield results.

- **Russia** – Russia acceded to the WIPO Internet Treaties, and has made progress combating software piracy. In addition, the Moscow City Government banned DVD/CD kiosks in the public transport system and pedestrian spaces, thus eliminating one major nexus of retail trade in pirated videos and music.
- **Chile** – Chile acceded to the Patent Cooperation Treaty. Chile also created a specialized brigade within the Chilean police force to handle IPR crimes.
- **Egypt** – In 2008, Egyptian courts issued the first jail sentences for IPR, in several criminal cases against defendants for software piracy.
- **India** – Due to the serious problem posed by counterfeit medicines, India passed the Drugs and Cosmetics (Amendment) Act 2008 that will increase penalties for spurious and adulterated pharmaceuticals. Additionally, India introduced an e-filing system for trademark and patent applications.
- **Indonesia** – A longstanding trademark dispute was resolved in 2008 after years of litigation.
- **Lebanon** – In 2008, Lebanon made significant progress on the long-standing problem of cable signal piracy, resulting in at least 80 percent of the 600-800 pirate cable operators signing licenses to become legitimate cable providers.
- **Saudi Arabia** – In 2008, Saudi Arabia established a website for its Violations Review Committee that provides information about copyright prosecutions and court cases and increases transparency for rightsholders.
- **Sweden** – In April 2009, a Swedish court convicted four defendants in connection with the PirateBay website, which was previously listed in the 2008 Special 301 Report as a notorious virtual market on the Internet. In addition, a new measure in Sweden permitting rightsholders in civil proceedings to obtain the identities of individuals implicated in the unauthorized exchange of digital content from ISPs entered into force.
- **Vietnam** – As part of its efforts to meet its obligations under the TRIPS Agreement, Vietnam passed a circular in 2008 to criminalize commercial scale copyright and trademark infringement.

The United States commends this positive progress by our trading partners. The United States will continue to work with these and other countries to achieve further improvements in IPR protection and enforcement during the coming year.