

## **SECTION I. DEVELOPMENTS IN INTELLECTUAL PROPERTY RIGHTS PROTECTION AND ENFORCEMENT**

An important part of the mission of the United States Trade Representative (USTR) is supporting and implementing the Administration's commitment to aggressively protect American intellectual property overseas. Infringement of intellectual property rights (IPR) causes significant financial losses for rights holders and legitimate businesses around the world. It undermines key U.S. comparative advantages in innovation and creativity to the detriment of American businesses and workers. In its most pernicious forms, it endangers the public. Some counterfeit products, such as automobile parts and medicines, pose significant risks to consumer health and safety. In addition, trade in counterfeit and pirated products often fuels cross-border organized criminal networks and hinders the sustainable economic development of many countries.

Because fostering innovation and creativity is essential to our prosperity, competitiveness, and the support of countless jobs in the United States, USTR works to protect American inventiveness and creativity with all the tools of U.S. trade policy, including this Report.

### **Initiative for Special 301 Action Plans**

The United States develops action plans and similar programs to address IPR issues in various contexts, including the Special 301 process. These plans and programs establish benchmarks, such as legislative, policy, or regulatory action by which to measure progress. Additionally, these plans can serve as tools to encourage U.S. trading partners to make improvements to their IPR regimes, thereby increasing the likelihood that they may be removed from the Special 301 list.

As called for in the Administration's 2010 Joint Strategic Plan on IPR Enforcement, USTR, in coordination with the Intellectual Property Enforcement Coordinator (IPEC), initiated an interagency process to increase the effectiveness of, and strengthen implementation of Special 301 action plans.

As a result of that process, **USTR is announcing that it invites any trading partner appearing on the Special 301 Priority Watch List or Watch List to work with the United States to develop a mutually agreed action plan designed to lead to that trading partner's removal from the relevant list.** Agreement on such a plan will not by itself change a trading partner's status in the Special 301 Report. However, in the past, successful completion of action plans has led to the removal of trading partners such as Saudi Arabia, Taiwan, and many others from Special 301 lists. An action plan may take more than one year to complete. Action plans differ from OCRs, which are conducted between Special 301 annual reports.

### **Positive Developments**

The United States welcomes the following important steps by our trading partners in 2010 and early 2011:

- **Australia, Canada, the European Union (EU) and its Member States, Japan, Korea, Mexico, Morocco, New Zealand, Singapore, Switzerland** – These trading partners, along with the United States, worked cooperatively to finalize the text of the Anti-Counterfeiting Trade Agreement – an important new tool to fight trademark counterfeiting and copyright piracy.

- **Mexico** – Mexico enacted legislation granting *ex officio* authority to its law enforcement officials to initiate criminal investigations against trademark counterfeiting and copyright piracy without requiring the rights holder to first file a complaint.
- **Philippines** – The Philippines enacted legislation to address unauthorized camcording of motion pictures in theaters.
- **Russia** – Russia enacted four pieces of IPR legislation, which complete the legislative commitments it made in the 2006 Bilateral Agreement on Protection and Enforcement of Intellectual Property Rights. These measures are: (1) amendments to Part IV of the Civil Code (governing intellectual property generally); (2) enactment of the Federal Law on Customs Regulation granting *ex officio* authority to customs officials; (3) amendments to the Law on Activity Licensing, which ensures that infringers cannot renew optical media production licenses; and (4) amendments to the Law on Circulation of Medicines to protect undisclosed test or other undisclosed data generated to obtain marketing approval.
- **Spain** – Spain took action to address the problem of copyright piracy over the Internet by passing legislation that will provide a mechanism for rights holders to remove or block access to infringing content online.

The United States will continue to work with its trading partners to further enhance IPR protection and enforcement during the coming year.

### **Initiatives to Strengthen IPR Protection and Enforcement 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:

- **Anti-Counterfeiting Trade Agreement (ACTA):** The ACTA negotiations, which concluded in November 2010, reflect a commitment by the negotiating parties not only to have strong laws on the books, but also to pursue the international cooperation and meaningful enforcement practices necessary to make intellectual property protection effective. ACTA will be the first agreement of its kind to both require strong enforcement provisions and promote the cooperation and key practices that make these provisions effective, raising international standards for the enforcement of IPR.
- **Trans-Pacific Partnership Agreement (TPP):** The TPP is a key initiative through which the United States seeks to advance the multi-faceted U.S. trade and investment interests in the Asia-Pacific region by negotiating an ambitious, 21st-century regional trade agreement along with Australia, Brunei Darussalam, Chile, Malaysia, New Zealand, Peru, Singapore, and Vietnam. The TPP negotiations have begun with this initial group of like-minded countries with the goal of creating a platform for integration across the region, and the TPP will include strong standards for the protection and enforcement of IPR.
- **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; the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council); and WTO dispute settlement.
- **Bilateral and Regional Initiatives:** The United States works 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 numerous trading partners, including in the Middle East and Asia, have facilitated discussions on enhancing IPR protection and enforcement.

- **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) program, and regional programs including the Caribbean Basin Economic Recovery Act (CBERA). USTR will continue to review IPR practices in Russia, Lebanon, and Uzbekistan under ongoing GSP reviews, in anticipation of the reauthorization of the GSP program.
- **Expanded International Cooperation:** USTR, in coordination with other agencies, looks forward to continuing engagement with trading partners in bilateral, regional, and multilateral fora to improve the global IPR environment. In addition to the work described above, the United States anticipates engaging with its trading partners in initiatives such as the U.S.-EU Summit, and in the Asia Pacific Economic Cooperation (APEC) forum, the Organization for Economic Cooperation and Development (OECD), and other multilateral and regional fora.

### **Best Practices by Trading Partners – IPR Enforcement**

Pursuant to the Administration’s Joint Strategic Plan on IP Enforcement, USTR is highlighting best practices by trading partners in the area of IPR enforcement. In comments submitted for this year’s Special 301 review process, stakeholders highlighted several key examples of best practices by U.S. trading partners:

- Stakeholders report that where foreign governments are open and transparent in bringing about legislative or regulatory change, and where such governments ensure that there is open dialogue between government officials and affected parties, it is easier for those stakeholders to comply with legislative or regulatory changes. Trading partners commended for improved cooperation and stakeholder engagement include Argentina, Canada, Guatemala, Italy, Malaysia, Mexico, and Pakistan, among others.
- Another important best practice may be found in trading partners’ efforts to tackle new challenges in IPR protection and enforcement. For example, industry reports positive efforts by China in tackling the serious problem of counterfeit drugs available through online advertisements and “Internet pharmacies” by working across ministries to target websites that knowingly violate local IPR laws. There were also positive reports regarding Russia’s efforts to combat counterfeit medicines through a Memorandum of Understanding between the Ministry of Health and the Federal Service for Intellectual Property.
- Finally, a significant best practice is the active participation of government officials in capacity building efforts and training. As further explained below, the United States strongly encourages foreign governments to make training opportunities available to their officials, and it actively engages with its trading partners in capacity building efforts both in the United States and abroad.

## Capacity Building Efforts

In addition to identifying concerns, this Report also highlights opportunities for the U.S. Government to work closely with trading partners to address those concerns. The U.S. Government collaborates with various trading partners on IPR related training and capacity building around the world. Both domestically and abroad, bilaterally and in regional groupings, the U.S. Government remains engaged in building stronger, more streamlined, and more effective systems for the protection and enforcement of IPR.

For example, in the United States, the U.S. Patent and Trademark Office (USPTO) invites officials from around the world for training at its Global Intellectual Property Academy, which conducts over 75 programs per year, training more than 4,500 participants from over 120 trading partners. These programs focus on a variety of topics, including patent and trademark examination, copyright, industrial designs, IPR management, and technology transfer. Furthermore, over half of the USPTO programs are directed to IPR enforcement capacity building, on topics such as border enforcement, prosecution practices, and judicial development. Other U.S. Government agencies bring foreign government and private-sector representatives to the United States on study tours to meet with IPR professionals and to visit the institutions and businesses responsible for developing, protecting, and promoting IPR in the United States. One such program is the State Department's International Visitors Leadership Program, which brings groups from around the world to cities across the United States to learn more about IPR and related trade and business issues. In addition, U.S. Government agencies, such as the State Department and the U.S. Copyright Office, conduct well-attended conferences in Washington.

Overseas, the U.S. Government is also active in partnering to provide training, technical assistance, capacity building, exchange of best practices, and other collaborative activities to improve IPR protection and enforcement. These activities are conducted by a number of U.S. Government agencies. For example:

- The USPTO's Office of Policy and External Affairs provides capacity building in countries around the world and has developed agreements with more than 40 national, regional, and international IPR organizations, such as the Caribbean Community (CARICOM), the Association of Southeast Asian Nations (ASEAN), the African Regional Intellectual Property Organization (ARIPO), the World Intellectual Property Organization (WIPO), the International Union for the Protection of New Varieties of Plants (UPOV), and Interpol, to partner on IPR training activities. These partnerships help ensure that capacity building and training efforts are demand-driven and meet the particular needs of each organization and trading partner.
- The Department of Commerce's International Trade Administration (ITA) collaborates with the private sector to develop programs to heighten the awareness of the dangers of counterfeit products and of the economic value of IPR to national economies. Additionally, ITA develops and shares small business tools to help domestic and foreign businesses understand the basics of IPR.

- In 2010, the Department of Homeland Security's (DHS) bureau of Customs and Border Protection (CBP) conducted regional border trainings programs that focused on IPR enforcement in Angola, Brunei, Egypt, Mali, Peru, Ukraine, and Thailand.
- The Department of State provides training funds each year to U.S. Government agencies that provide IPR enforcement training and technical assistance to foreign governments. The agencies that provide such training include the U.S. Department of Justice (DOJ), the USPTO, CBP and DHS's Immigrations and Customs Enforcement bureau. In 2010, the State Department provided funds for 11 training programs for customs, police, and judicial officials from various trading partners including Indonesia, Mexico, Russia, and Vietnam, as well as regional groups, including ASEAN, and through regional trainings in the South Asia region, including India, and in sub-Saharan Africa. The U.S. Government works collaboratively on many of these training programs with the private sector and with various international entities such as WIPO, and with regional organizations, such as the APEC Intellectual Property Experts Group.
- The Department of Commerce's Commercial Law Development Program (CLDP) provides training to foreign lawmakers, regulators, judges, and educators focused on IPR enforcement. CLDP currently works with more than 35 governments and has conducted cooperative programs in Central and Eastern Europe, the Commonwealth of Independent States (CIS), the Middle East, North Africa, Sub-Saharan Africa, and Asia. For example, since 2009, CLDP has organized annual judicial capacity building programs in Bosnia-Herzegovina focused on the fair, predictable, and efficient adjudication of intellectual property cases. In Egypt, CLDP conducted a two-day training workshop in December 2010 at the Internal Trade Development Authority for trademark officers and board of appeals judges to provide an overview of the trademark system in the United States, and to address various topics, including the likelihood of confusion standard, distinctiveness of marks, and registration of trade dress. In Pakistan, CLDP has trained justices from Pakistan's national and regional supreme courts on IPR enforcement. In Sub-Saharan Africa, CLDP organized interagency bilateral IPR enforcement programs in Ghana, Liberia, and Mali, and regional IPR programs in Botswana, Senegal, and Uganda.

Although many trading partners have implemented IPR legislation, a lack of criminal prosecutions and deterrent sentencing has reduced the effectiveness of IPR enforcement in many regions. These problems result from several factors, including a lack of knowledge of IPR law on the part of judges and enforcement officials, and insufficient enforcement resources. The United States welcomes steps by a number of trading partners to educate their judiciary and enforcement officials on IPR matters. The United States will continue to work collaboratively with trading partners to address these issues.

### **Trends in Trademark Counterfeiting and Copyright Piracy**

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 medicines, health care products, food

and beverages, automobile and airplane parts, toothpaste, shampoos, razors, electronics, batteries, chemicals, and sporting goods.

Counterfeiting and piracy diminish the profits of legitimate producers and risk harm to consumers who may purchase fraudulent, potentially dangerous products. Trading partners where rampant counterfeiting and piracy occur lose tax revenue and may find it more difficult to attract investment. Those engaged in trademark counterfeiting and piracy 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 and piracy that include:

- A greater variety in the types of goods that are being counterfeited, as well as the production of labels and components for these fake products. Counterfeiters are establishing a global trade in counterfeit items, shipping them separately to free trade zones (FTZs) to be assembled and distributed in another country. Counterfeiters have also abused FTZs to disguise the origin of counterfeit goods.
- A rapid growth in the piracy of copyrighted products in virtually all formats, as well as counterfeiting of trademarked goods, because these criminal enterprises offer enormous profits and little risk. Such enterprises require little up-front capital investment, and even if they are detected and prosecuted, the penalties imposed on them in many countries are so low that such penalties offer little or no deterrence against further infringements and are viewed merely as a cost of doing business.
- A growth in the online sale of pirated and counterfeit hard goods that is rapidly approaching the volume of goods that sold by street vendors and in other physical markets. Legal and investigative institutions face difficulties in responding to this trend. Online advertisements for sale of unlawful physical goods that are delivered through the mail or by hand are found in many places, including China, France, Germany, Japan, Spain, and Taiwan. For example, in China, although the largest Internet-based sales portals have responded to rights holders' complaints of counterfeit and pirated product listings, and even though major online sellers and distributors seem to be making efforts to ensure that the content available on their websites is legal, more than 75 percent of illicit sellers have reportedly re-listed the infringing goods.
- Another notable trend involves shipping counterfeit products separately from labels and packaging to evade enforcement efforts. For example, infringers in Russia reportedly import unbranded products, package these products with unauthorized packaging materials bearing the rights holders' trademarks, and subsequently export the products to various countries. Infringers in countries such as Paraguay reportedly facilitate these illegal activities by exporting label and packaging components to these counterfeit and pirated product assemblers. There are reports of transit of illicit labels through other countries as well, including Mexico and the Philippines.

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 ensure that penalties have deterrent effects, and include significant monetary fines and meaningful sentences of imprisonment.

Additionally, important elements of a deterrent enforcement system include requirements that pirated and counterfeit goods, as well as materials and implements used for their production, are seized and destroyed.

The manufacture and distribution of pharmaceutical products bearing counterfeit trademarks is a growing problem that has important consequences for consumer health and safety. Such trademark counterfeiting is one dimension of the larger problem of substandard medicines. The United States notes its particular concern with the proliferation of the manufacture, sale, and distribution of counterfeit pharmaceuticals in countries such as Brazil, China, India, Indonesia, Lebanon, Peru, and Russia.

In many cases, bulk active pharmaceutical ingredients (API) that are used to manufacture pharmaceuticals that bear counterfeit trademarks are not made according to good manufacturing practices. Hence, these products may contain sub-standard and potentially hazardous materials. For instance, in China, domestic chemical manufacturers that produce APIs can avoid regulatory oversight by failing to declare that the bulk chemical is intended for use in pharmaceutical products. This factor contributes to China being a major source country for APIs used in counterfeit pharmaceutical products. Although China has taken some welcome steps, such as requiring manufacturers to register with the State Food and Drug Administration, more effective regulatory controls are needed to assist China and its trading partners in their efforts to address this problem.

### **Piracy Over the Internet and Digital Piracy**

The increased availability of broadband Internet connections around the world is generating many benefits, from increased economic activity and new online business models to greater access to and exchange of information. However, this phenomenon has also made the Internet an extremely efficient vehicle for disseminating copyright-infringing products.

Piracy over the Internet is a significant concern with respect to a number of trading partners, including Brazil, Canada, China, India, Italy, Russia, Spain, and Ukraine. Unauthorized retransmission of live sports telecasts over the Internet continues to be a growing problem for many trading partners, particularly in China, and “linking sites” are exacerbating the problem. In addition, piracy using new technologies is an emerging problem internationally. U.S. copyright industries also report growing problems with piracy using mobile telephones, tablets, 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, “apps”, games, and scanned books also occurs. Recent developments include the creation of “hybrid” websites that offer counterfeit goods in addition to pirated copyrighted works, in an effort to create a “one-stop-shop” for users looking for cheap or free content or goods. The United States will work with its trading partners to combat these growing problems. The United States urges trading partners to adequately implement the WIPO Internet Treaties, which provide tools necessary for protecting copyrighted works in the digital environment.

To encourage strong action against piracy over the Internet, the United States will seek to work with the following trading partners to strengthen legal regimes and enhance enforcement: Argentina, Belarus, Brazil, Brunei, Canada, Colombia, India, Italy, Malaysia, Mexico, Philippines, Romania, Russia, Spain, Thailand, Turkey, Ukraine, Venezuela, and Vietnam. In particular, the United States

will encourage trading partners implement the WIPO Internet Treaties, including by providing protection against the circumvention of technological protection measures. The United States also encourages trading partners to adopt appropriate measures where needed with respect to the unauthorized camcording of motion pictures in theaters. In addition, the United States will encourage trading partners to enhance enforcement efforts including, for example, through the following: strengthening enforcement against major channels of piracy over the Internet, including notorious markets; creating specialized enforcement units or undertaking special initiatives against piracy over the Internet; and undertaking training to strengthen capacity to fight piracy over the Internet.

Although piracy over the Internet is rapidly supplanting physical piracy in many markets around the world, the production of, and trade in, pirated optical discs remain major problems in many regions. In recent years, some trading partners, such as the Czech Republic, Poland, Romania, and Russia, have made progress toward implementing controls on optical media production. Other trading partners still need to adopt and implement legislation or improve existing measures to combat illegal optical disc production and distribution, including China, India, Paraguay, Thailand, and Vietnam. The United States continues to urge its trading partners who face challenges of illegal optical disc production to pass effective legislation to counter this problem, and to enforce existing laws and regulations aggressively.

### **Trademarks and Domain Name Disputes**

A growing area of concern for trademark holders is the protection of their trademarks against unauthorized uses under country code top level domain name (ccTLD) extensions. U.S. rights holders risk losing valuable Internet traffic because of such uses. A related and growing concern is that ccTLDs lack transparent and predictable uniform domain name dispute resolution policies (UDRPs). Effective UDRPs should assist in the quick and efficient resolution of these disputes. The United States encourages its trading partners to provide procedures that allow for the protection of trademarks used in domain names, and to ensure that dispute resolution procedures are available to effectively enforce against misuse of trademarks.

### **Government Use of Software**

Under Executive Order 13103 issued in September 1998, U.S. Government agencies maintain procedures to ensure that they use only authorized 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 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 trading partners mandating that only authorized, legitimate software may be used by their government bodies. Further work on this issue remains with certain trading partners, such as China, Costa Rica, India, Pakistan, Paraguay, Peru, Tajikistan, and Ukraine. The United States looks forward to these trading partners' adoption of effective and transparent procedures to ensure legitimate governmental use of software.



## **SECTION I. DEVELOPMENTS IN INTELLECTUAL PROPERTY RIGHTS PROTECTION AND ENFORCEMENT**

An important part of the mission of the United States Trade Representative (USTR) is supporting and implementing the Administration's commitment to aggressively protect American intellectual property overseas. Infringement of intellectual property rights (IPR) causes significant financial losses for rights holders and legitimate businesses around the world. It undermines key U.S. comparative advantages in innovation and creativity to the detriment of American businesses and workers. In its most pernicious forms, it endangers the public. Some counterfeit products, such as automobile parts and medicines, pose significant risks to consumer health and safety. In addition, trade in counterfeit and pirated products often fuels cross-border organized criminal networks and hinders the sustainable economic development of many countries.

Because fostering innovation and creativity is essential to our prosperity, competitiveness, and the support of countless jobs in the United States, USTR works to protect American inventiveness and creativity with all the tools of U.S. trade policy, including this Report.

### **Initiative for Special 301 Action Plans**

The United States develops action plans and similar programs to address IPR issues in various contexts, including the Special 301 process. These plans and programs establish benchmarks, such as legislative, policy, or regulatory action by which to measure progress. Additionally, these plans can serve as tools to encourage U.S. trading partners to make improvements to their IPR regimes, thereby increasing the likelihood that they may be removed from the Special 301 list.

As called for in the Administration's 2010 Joint Strategic Plan on IPR Enforcement, USTR, in coordination with the Intellectual Property Enforcement Coordinator (IPEC), initiated an interagency process to increase the effectiveness of, and strengthen implementation of Special 301 action plans.

As a result of that process, **USTR is announcing that it invites any trading partner appearing on the Special 301 Priority Watch List or Watch List to work with the United States to develop a mutually agreed action plan designed to lead to that trading partner's removal from the relevant list.** Agreement on such a plan will not by itself change a trading partner's status in the Special 301 Report. However, in the past, successful completion of action plans has led to the removal of trading partners such as Saudi Arabia, Taiwan, and many others from Special 301 lists. An action plan may take more than one year to complete. Action plans differ from OCRs, which are conducted between Special 301 annual reports.

### **Positive Developments**

The United States welcomes the following important steps by our trading partners in 2010 and early 2011:

- **Australia, Canada, the European Union (EU) and its Member States, Japan, Korea, Mexico, Morocco, New Zealand, Singapore, Switzerland** – These trading partners, along with the United States, worked cooperatively to finalize the text of the Anti-Counterfeiting Trade Agreement – an important new tool to fight trademark counterfeiting and copyright piracy.

- **Mexico** – Mexico enacted legislation granting *ex officio* authority to its law enforcement officials to initiate criminal investigations against trademark counterfeiting and copyright piracy without requiring the rights holder to first file a complaint.
- **Philippines** – The Philippines enacted legislation to address unauthorized camcording of motion pictures in theaters.
- **Russia** – Russia enacted four pieces of IPR legislation, which complete the legislative commitments it made in the 2006 Bilateral Agreement on Protection and Enforcement of Intellectual Property Rights. These measures are: (1) amendments to Part IV of the Civil Code (governing intellectual property generally); (2) enactment of the Federal Law on Customs Regulation granting *ex officio* authority to customs officials; (3) amendments to the Law on Activity Licensing, which ensures that infringers cannot renew optical media production licenses; and (4) amendments to the Law on Circulation of Medicines to protect undisclosed test or other undisclosed data generated to obtain marketing approval.
- **Spain** – Spain took action to address the problem of copyright piracy over the Internet by passing legislation that will provide a mechanism for rights holders to remove or block access to infringing content online.

The United States will continue to work with its trading partners to further enhance IPR protection and enforcement during the coming year.

### **Initiatives to Strengthen IPR Protection and Enforcement 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:

- **Anti-Counterfeiting Trade Agreement (ACTA):** The ACTA negotiations, which concluded in November 2010, reflect a commitment by the negotiating parties not only to have strong laws on the books, but also to pursue the international cooperation and meaningful enforcement practices necessary to make intellectual property protection effective. ACTA will be the first agreement of its kind to both require strong enforcement provisions and promote the cooperation and key practices that make these provisions effective, raising international standards for the enforcement of IPR.
- **Trans-Pacific Partnership Agreement (TPP):** The TPP is a key initiative through which the United States seeks to advance the multi-faceted U.S. trade and investment interests in the Asia-Pacific region by negotiating an ambitious, 21st-century regional trade agreement along with Australia, Brunei Darussalam, Chile, Malaysia, New Zealand, Peru, Singapore, and Vietnam. The TPP negotiations have begun with this initial group of like-minded countries with the goal of creating a platform for integration across the region, and the TPP will include strong standards for the protection and enforcement of IPR.
- **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; the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council); and WTO dispute settlement.
- **Bilateral and Regional Initiatives:** The United States works 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 numerous trading partners, including in the Middle East and Asia, have facilitated discussions on enhancing IPR protection and enforcement.

- **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) program, and regional programs including the Caribbean Basin Economic Recovery Act (CBERA). USTR will continue to review IPR practices in Russia, Lebanon, and Uzbekistan under ongoing GSP reviews, in anticipation of the reauthorization of the GSP program.
- **Expanded International Cooperation:** USTR, in coordination with other agencies, looks forward to continuing engagement with trading partners in bilateral, regional, and multilateral fora to improve the global IPR environment. In addition to the work described above, the United States anticipates engaging with its trading partners in initiatives such as the U.S.-EU Summit, and in the Asia Pacific Economic Cooperation (APEC) forum, the Organization for Economic Cooperation and Development (OECD), and other multilateral and regional fora.

### **Best Practices by Trading Partners – IPR Enforcement**

Pursuant to the Administration’s Joint Strategic Plan on IP Enforcement, USTR is highlighting best practices by trading partners in the area of IPR enforcement. In comments submitted for this year’s Special 301 review process, stakeholders highlighted several key examples of best practices by U.S. trading partners:

- Stakeholders report that where foreign governments are open and transparent in bringing about legislative or regulatory change, and where such governments ensure that there is open dialogue between government officials and affected parties, it is easier for those stakeholders to comply with legislative or regulatory changes. Trading partners commended for improved cooperation and stakeholder engagement include Argentina, Canada, Guatemala, Italy, Malaysia, Mexico, and Pakistan, among others.
- Another important best practice may be found in trading partners’ efforts to tackle new challenges in IPR protection and enforcement. For example, industry reports positive efforts by China in tackling the serious problem of counterfeit drugs available through online advertisements and “Internet pharmacies” by working across ministries to target websites that knowingly violate local IPR laws. There were also positive reports regarding Russia’s efforts to combat counterfeit medicines through a Memorandum of Understanding between the Ministry of Health and the Federal Service for Intellectual Property.
- Finally, a significant best practice is the active participation of government officials in capacity building efforts and training. As further explained below, the United States strongly encourages foreign governments to make training opportunities available to their officials, and it actively engages with its trading partners in capacity building efforts both in the United States and abroad.

## Capacity Building Efforts

In addition to identifying concerns, this Report also highlights opportunities for the U.S. Government to work closely with trading partners to address those concerns. The U.S. Government collaborates with various trading partners on IPR related training and capacity building around the world. Both domestically and abroad, bilaterally and in regional groupings, the U.S. Government remains engaged in building stronger, more streamlined, and more effective systems for the protection and enforcement of IPR.

For example, in the United States, the U.S. Patent and Trademark Office (USPTO) invites officials from around the world for training at its Global Intellectual Property Academy, which conducts over 75 programs per year, training more than 4,500 participants from over 120 trading partners. These programs focus on a variety of topics, including patent and trademark examination, copyright, industrial designs, IPR management, and technology transfer. Furthermore, over half of the USPTO programs are directed to IPR enforcement capacity building, on topics such as border enforcement, prosecution practices, and judicial development. Other U.S. Government agencies bring foreign government and private-sector representatives to the United States on study tours to meet with IPR professionals and to visit the institutions and businesses responsible for developing, protecting, and promoting IPR in the United States. One such program is the State Department's International Visitors Leadership Program, which brings groups from around the world to cities across the United States to learn more about IPR and related trade and business issues. In addition, U.S. Government agencies, such as the State Department and the U.S. Copyright Office, conduct well-attended conferences in Washington.

Overseas, the U.S. Government is also active in partnering to provide training, technical assistance, capacity building, exchange of best practices, and other collaborative activities to improve IPR protection and enforcement. These activities are conducted by a number of U.S. Government agencies. For example:

- The USPTO's Office of Policy and External Affairs provides capacity building in countries around the world and has developed agreements with more than 40 national, regional, and international IPR organizations, such as the Caribbean Community (CARICOM), the Association of Southeast Asian Nations (ASEAN), the African Regional Intellectual Property Organization (ARIPO), the World Intellectual Property Organization (WIPO), the International Union for the Protection of New Varieties of Plants (UPOV), and Interpol, to partner on IPR training activities. These partnerships help ensure that capacity building and training efforts are demand-driven and meet the particular needs of each organization and trading partner.
- The Department of Commerce's International Trade Administration (ITA) collaborates with the private sector to develop programs to heighten the awareness of the dangers of counterfeit products and of the economic value of IPR to national economies. Additionally, ITA develops and shares small business tools to help domestic and foreign businesses understand the basics of IPR.

- In 2010, the Department of Homeland Security's (DHS) bureau of Customs and Border Protection (CBP) conducted regional border trainings programs that focused on IPR enforcement in Angola, Brunei, Egypt, Mali, Peru, Ukraine, and Thailand.
- The Department of State provides training funds each year to U.S. Government agencies that provide IPR enforcement training and technical assistance to foreign governments. The agencies that provide such training include the U.S. Department of Justice (DOJ), the USPTO, CBP and DHS's Immigrations and Customs Enforcement bureau. In 2010, the State Department provided funds for 11 training programs for customs, police, and judicial officials from various trading partners including Indonesia, Mexico, Russia, and Vietnam, as well as regional groups, including ASEAN, and through regional trainings in the South Asia region, including India, and in sub-Saharan Africa. The U.S. Government works collaboratively on many of these training programs with the private sector and with various international entities such as WIPO, and with regional organizations, such as the APEC Intellectual Property Experts Group.
- The Department of Commerce's Commercial Law Development Program (CLDP) provides training to foreign lawmakers, regulators, judges, and educators focused on IPR enforcement. CLDP currently works with more than 35 governments and has conducted cooperative programs in Central and Eastern Europe, the Commonwealth of Independent States (CIS), the Middle East, North Africa, Sub-Saharan Africa, and Asia. For example, since 2009, CLDP has organized annual judicial capacity building programs in Bosnia-Herzegovina focused on the fair, predictable, and efficient adjudication of intellectual property cases. In Egypt, CLDP conducted a two-day training workshop in December 2010 at the Internal Trade Development Authority for trademark officers and board of appeals judges to provide an overview of the trademark system in the United States, and to address various topics, including the likelihood of confusion standard, distinctiveness of marks, and registration of trade dress. In Pakistan, CLDP has trained justices from Pakistan's national and regional supreme courts on IPR enforcement. In Sub-Saharan Africa, CLDP organized interagency bilateral IPR enforcement programs in Ghana, Liberia, and Mali, and regional IPR programs in Botswana, Senegal, and Uganda.

Although many trading partners have implemented IPR legislation, a lack of criminal prosecutions and deterrent sentencing has reduced the effectiveness of IPR enforcement in many regions. These problems result from several factors, including a lack of knowledge of IPR law on the part of judges and enforcement officials, and insufficient enforcement resources. The United States welcomes steps by a number of trading partners to educate their judiciary and enforcement officials on IPR matters. The United States will continue to work collaboratively with trading partners to address these issues.

### **Trends in Trademark Counterfeiting and Copyright Piracy**

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 medicines, health care products, food

and beverages, automobile and airplane parts, toothpaste, shampoos, razors, electronics, batteries, chemicals, and sporting goods.

Counterfeiting and piracy diminish the profits of legitimate producers and risk harm to consumers who may purchase fraudulent, potentially dangerous products. Trading partners where rampant counterfeiting and piracy occur lose tax revenue and may find it more difficult to attract investment. Those engaged in trademark counterfeiting and piracy 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 and piracy that include:

- A greater variety in the types of goods that are being counterfeited, as well as the production of labels and components for these fake products. Counterfeiters are establishing a global trade in counterfeit items, shipping them separately to free trade zones (FTZs) to be assembled and distributed in another country. Counterfeiters have also abused FTZs to disguise the origin of counterfeit goods.
- A rapid growth in the piracy of copyrighted products in virtually all formats, as well as counterfeiting of trademarked goods, because these criminal enterprises offer enormous profits and little risk. Such enterprises require little up-front capital investment, and even if they are detected and prosecuted, the penalties imposed on them in many countries are so low that such penalties offer little or no deterrence against further infringements and are viewed merely as a cost of doing business.
- A growth in the online sale of pirated and counterfeit hard goods that is rapidly approaching the volume of goods that sold by street vendors and in other physical markets. Legal and investigative institutions face difficulties in responding to this trend. Online advertisements for sale of unlawful physical goods that are delivered through the mail or by hand are found in many places, including China, France, Germany, Japan, Spain, and Taiwan. For example, in China, although the largest Internet-based sales portals have responded to rights holders' complaints of counterfeit and pirated product listings, and even though major online sellers and distributors seem to be making efforts to ensure that the content available on their websites is legal, more than 75 percent of illicit sellers have reportedly re-listed the infringing goods.
- Another notable trend involves shipping counterfeit products separately from labels and packaging to evade enforcement efforts. For example, infringers in Russia reportedly import unbranded products, package these products with unauthorized packaging materials bearing the rights holders' trademarks, and subsequently export the products to various countries. Infringers in countries such as Paraguay reportedly facilitate these illegal activities by exporting label and packaging components to these counterfeit and pirated product assemblers. There are reports of transit of illicit labels through other countries as well, including Mexico and the Philippines.

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 ensure that penalties have deterrent effects, and include significant monetary fines and meaningful sentences of imprisonment.

Additionally, important elements of a deterrent enforcement system include requirements that pirated and counterfeit goods, as well as materials and implements used for their production, are seized and destroyed.

The manufacture and distribution of pharmaceutical products bearing counterfeit trademarks is a growing problem that has important consequences for consumer health and safety. Such trademark counterfeiting is one dimension of the larger problem of substandard medicines. The United States notes its particular concern with the proliferation of the manufacture, sale, and distribution of counterfeit pharmaceuticals in countries such as Brazil, China, India, Indonesia, Lebanon, Peru, and Russia.

In many cases, bulk active pharmaceutical ingredients (API) that are used to manufacture pharmaceuticals that bear counterfeit trademarks are not made according to good manufacturing practices. Hence, these products may contain sub-standard and potentially hazardous materials. For instance, in China, domestic chemical manufacturers that produce APIs can avoid regulatory oversight by failing to declare that the bulk chemical is intended for use in pharmaceutical products. This factor contributes to China being a major source country for APIs used in counterfeit pharmaceutical products. Although China has taken some welcome steps, such as requiring manufacturers to register with the State Food and Drug Administration, more effective regulatory controls are needed to assist China and its trading partners in their efforts to address this problem.

### **Piracy Over the Internet and Digital Piracy**

The increased availability of broadband Internet connections around the world is generating many benefits, from increased economic activity and new online business models to greater access to and exchange of information. However, this phenomenon has also made the Internet an extremely efficient vehicle for disseminating copyright-infringing products.

Piracy over the Internet is a significant concern with respect to a number of trading partners, including Brazil, Canada, China, India, Italy, Russia, Spain, and Ukraine. Unauthorized retransmission of live sports telecasts over the Internet continues to be a growing problem for many trading partners, particularly in China, and “linking sites” are exacerbating the problem. In addition, piracy using new technologies is an emerging problem internationally. U.S. copyright industries also report growing problems with piracy using mobile telephones, tablets, 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, “apps”, games, and scanned books also occurs. Recent developments include the creation of “hybrid” websites that offer counterfeit goods in addition to pirated copyrighted works, in an effort to create a “one-stop-shop” for users looking for cheap or free content or goods. The United States will work with its trading partners to combat these growing problems. The United States urges trading partners to adequately implement the WIPO Internet Treaties, which provide tools necessary for protecting copyrighted works in the digital environment.

To encourage strong action against piracy over the Internet, the United States will seek to work with the following trading partners to strengthen legal regimes and enhance enforcement: Argentina, Belarus, Brazil, Brunei, Canada, Colombia, India, Italy, Malaysia, Mexico, Philippines, Romania, Russia, Spain, Thailand, Turkey, Ukraine, Venezuela, and Vietnam. In particular, the United States

will encourage trading partners implement the WIPO Internet Treaties, including by providing protection against the circumvention of technological protection measures. The United States also encourages trading partners to adopt appropriate measures where needed with respect to the unauthorized camcording of motion pictures in theaters. In addition, the United States will encourage trading partners to enhance enforcement efforts including, for example, through the following: strengthening enforcement against major channels of piracy over the Internet, including notorious markets; creating specialized enforcement units or undertaking special initiatives against piracy over the Internet; and undertaking training to strengthen capacity to fight piracy over the Internet.

Although piracy over the Internet is rapidly supplanting physical piracy in many markets around the world, the production of, and trade in, pirated optical discs remain major problems in many regions. In recent years, some trading partners, such as the Czech Republic, Poland, Romania, and Russia, have made progress toward implementing controls on optical media production. Other trading partners still need to adopt and implement legislation or improve existing measures to combat illegal optical disc production and distribution, including China, India, Paraguay, Thailand, and Vietnam. The United States continues to urge its trading partners who face challenges of illegal optical disc production to pass effective legislation to counter this problem, and to enforce existing laws and regulations aggressively.

### **Trademarks and Domain Name Disputes**

A growing area of concern for trademark holders is the protection of their trademarks against unauthorized uses under country code top level domain name (ccTLD) extensions. U.S. rights holders risk losing valuable Internet traffic because of such uses. A related and growing concern is that ccTLDs lack transparent and predictable uniform domain name dispute resolution policies (UDRPs). Effective UDRPs should assist in the quick and efficient resolution of these disputes. The United States encourages its trading partners to provide procedures that allow for the protection of trademarks used in domain names, and to ensure that dispute resolution procedures are available to effectively enforce against misuse of trademarks.

### **Government Use of Software**

Under Executive Order 13103 issued in September 1998, U.S. Government agencies maintain procedures to ensure that they use only authorized 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 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 trading partners mandating that only authorized, legitimate software may be used by their government bodies. Further work on this issue remains with certain trading partners, such as China, Costa Rica, India, Pakistan, Paraguay, Peru, Tajikistan, and Ukraine. The United States looks forward to these trading partners' adoption of effective and transparent procedures to ensure legitimate governmental use of software.



## **Intellectual Property and Health Policy**

Numerous comments in the 2011 Special 301 review highlighted important concerns arising at the intersection of IPR policy and health policy. The 2001 WTO Doha Declaration on the TRIPS Agreement and Public Health recognized the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics. As affirmed in the Doha Declaration on TRIPS and Public Health, the United States respects a trading partner's right to protect public health and, 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 medicines. The assessments set forth in this Report are based on various critical factors, including, where relevant, the Doha Declaration on TRIPS and Public Health.

Consistent with these views, the United States respects its trading partners' rights to grant compulsory licenses, in a manner consistent with the provisions of the TRIPS Agreement, and encourages its trading partners to consider ways to address their public health challenges while maintaining 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 trading partners to address the serious public health problems that they may face. The United States strongly supports the WTO 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, 2011 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 its bilateral and regional trade agreements, as well as U.S. engagement in international organizations, including the United Nations and related institutions such as WIPO and the World Health Organization, are consistent with U.S. Government policies concerning intellectual property and health policy and do not impede its trading partners from taking measures necessary to protect public health. Accordingly, USTR will continue its close cooperation with relevant agencies, including the Department of Health and Human Services and the United States Agency for International Development, to ensure that public health challenges are addressed and IPR protection and enforcement is supported as a mechanism to promote research and innovation.

## **Supporting Pharmaceutical and Medical Device Innovation through Improved Market Access**

USTR has sought to reduce market access barriers that U.S. pharmaceutical and medical device companies face in many countries, and to facilitate both affordable health care today and the innovation that assures improved health care tomorrow. For example, this year's Special 301 Report

## **Intellectual Property and Health Policy**

Numerous comments in the 2011 Special 301 review highlighted important concerns arising at the intersection of IPR policy and health policy. The 2001 WTO Doha Declaration on the TRIPS Agreement and Public Health recognized the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics. As affirmed in the Doha Declaration on TRIPS and Public Health, the United States respects a trading partner's right to protect public health and, 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 medicines. The assessments set forth in this Report are based on various critical factors, including, where relevant, the Doha Declaration on TRIPS and Public Health.

Consistent with these views, the United States respects its trading partners' rights to grant compulsory licenses, in a manner consistent with the provisions of the TRIPS Agreement, and encourages its trading partners to consider ways to address their public health challenges while maintaining 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 trading partners to address the serious public health problems that they may face. The United States strongly supports the WTO 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, 2011 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 its bilateral and regional trade agreements, as well as U.S. engagement in international organizations, including the United Nations and related institutions such as WIPO and the World Health Organization, are consistent with U.S. Government policies concerning intellectual property and health policy and do not impede its trading partners from taking measures necessary to protect public health. Accordingly, USTR will continue its close cooperation with relevant agencies, including the Department of Health and Human Services and the United States Agency for International Development, to ensure that public health challenges are addressed and IPR protection and enforcement is supported as a mechanism to promote research and innovation.

## **Supporting Pharmaceutical and Medical Device Innovation through Improved Market Access**

USTR has sought to reduce market access barriers that U.S. pharmaceutical and medical device companies face in many countries, and to facilitate both affordable health care today and the innovation that assures improved health care tomorrow. For example, this year's Special 301 Report

highlights concerns regarding market access barriers affecting pharmaceutical products in Algeria and Indonesia.

Even where a trading partner's IPR regime demonstrates a commitment to strong IPR protection, other types of measures have the potential to affect market access in the pharmaceutical and medical device sector. For example, government practices including unreasonable regulatory approval delays and potentially unfair reimbursement policies can discourage the development of new drugs and other medical products. The criteria, rationale, and operation of such measures are often nontransparent or not fully disclosed to patients or to pharmaceutical and medical device companies seeking to market their products. USTR encourages trading partners to provide appropriate mechanisms for transparency, procedural and due process protections, and opportunities for public engagement in the context of their relevant health care systems.

U.S. industry has expressed concerns regarding the policies of several industrialized trading partners, including Finland, Germany, Greece, Japan, Korea, New Zealand, Poland, and Taiwan, on issues related to innovation in the pharmaceutical sector and other aspects of health care goods and services. Examples include:

- With respect to Japan, pharmaceutical and medical device issues are an integral part of regular bilateral discussions. While Japan has made progress on these issues, the United States continues to work with Japan to seek continued improvements in transparency in addition to further reform of reimbursement and regulatory systems that would facilitate the timely introduction of innovative pharmaceuticals and medical devices into Japan's market.
- With respect to Poland, U.S. industry is concerned about healthcare reform legislation introduced in 2010 that would alter Poland's pricing, reimbursement, and clinical trials policies. Industry continues to express concern about the pharmaceutical industry's general lack of ability to meet with the Ministry of Health to provide their perspectives on policy initiatives.
- With respect to New Zealand, U.S. industry has expressed serious concerns about the policies and operation of New Zealand's Pharmaceutical Management Agency (PhARMAC). Industry continues to express concerns regarding, among other things, the transparency, fairness, and predictability of the PHARMAC pricing and reimbursement regime, as well as the overall climate for innovative medicines in New Zealand.

The United States is seeking to establish or continue dialogues with relevant trading partners to address these and other sectoral concerns, and encourage a common understanding on questions related to innovation in the pharmaceutical and medical device sectors. For example, the United States-Korea Free Trade Agreement, once in force, would improve access to innovative medical products and ensure the transparent, predictable, and non-discriminatory pricing and reimbursement of innovative and generic pharmaceutical products, and medical devices. The United States is also continuing its engagement with China to promote fair and transparent policies in this sector.

The United States shares policy goals and concerns related to health care with other 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 the objective of delivering care in the most efficient and responsive way possible. The United States looks forward to engaging with these trading partners to address specific concerns related to reimbursements, regulatory policies, and transparency.

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

The TRIPS Agreement, one of the most significant achievements of the Uruguay Round, requires all WTO members to provide certain minimum standards of IPR protection and enforcement. 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 the TRIPS Agreement 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 and effective IPR enforcement mechanisms.

Recognizing the particular challenges faced by least-developed countries (LDCs), 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 LDC members in turn pledged to preserve the progress that some have already made toward TRIPS Agreement implementation. Additionally, the LDC members have until 2016 to implement their TRIPS Agreement 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 will continue to work with WTO members and expects further progress in the near term towards completing their TRIPS Agreement implementation process. However, in those instances in which additional progress is not achieved, the United States will consider alternative means of encouraging implementation, including the possibility of recourse to WTO dispute settlement.

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 Agreement implementation. Furthermore, the United States continues to work with other WTO members, including the EU, 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 to ensure 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 preferred manner of

resolving concerns is through bilateral dialogue. Where these efforts are unsuccessful, the United States will not hesitate to use the dispute settlement procedures, as appropriate.

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 finding in favor of the United States that found (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. On April 15, 2009, China notified the DSB that China intended to implement the recommendations and rulings of the DSB in this dispute, and stated it would need a reasonable period of time for implementation. On June 29, 2009, the United States and China notified the DSB that they had agreed on a one-year period of time for implementation, to end on March 20, 2010. On March 19, 2010, China announced that it had completed all the necessary domestic legislative procedures to implement the DSB recommendations and rulings. The United States continues to monitor China's implementation of the 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 distribution and market access for publications, movies, and music, and audio-visual home entertainment products (AVHE products). The U.S. claims challenged China's prohibition on foreign companies' importation of all products at issue; China's prohibitions and discriminatory requirements imposed on foreign distributors of publications, music, and AVHE products within China; and China's imposition of more burdensome requirements on the distribution of imported publications, movies, and music vis-à-vis their domestic counterparts. A WTO panel was established to examine this matter on November 27, 2007. On August 12, 2009, the panel found in favor of the United States on the vast majority of its claims. China subsequently appealed certain of the panel's findings. However, on December 21, 2009, the WTO Appellate Body rejected each of China's claims on appeal and sustained the panel's findings in those respects. On January 19, 2010, the DSB adopted the panel and Appellate Body reports. Despite its commitment to do so, China did not bring all of its measures into compliance with the DSB recommendations by the agreed-upon deadline of March 19, 2011. The United States is working closely with China to resolve the issues in this dispute on terms agreeable to both parties.

Following the 1999 Special 301 review, the United States initiated dispute settlement consultations concerning the 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 finding 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. On March 31, 2006, the EU 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 EU to address, and the United States intends to continue monitoring this situation.