INTELLECTUAL PROPERTY

Federal Enforcement Has Generally Increased, but Assessing Performance Could Strengthen Law Enforcement Efforts
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What GAO Found

Five key agencies play a role in IP enforcement, and their enforcement functions include seizures, investigations, and prosecutions (see figure below). While IP enforcement is generally not their highest priority, IP crimes with a public health and safety risk, such as production of counterfeit pharmaceuticals, is an IP enforcement priority at each agency. Determining agencies’ IP enforcement resources is challenging because few staff are dedicated to this area, and not all agencies track staff time spent on IP enforcement. Agencies carry out some enforcement actions through their headquarters, but significant enforcement takes place in the field.

Federal enforcement actions generally increased during fiscal years 2001-2006, but the key agencies have not taken key steps to assess their achievements. For example, most have not systematically analyzed their IP enforcement statistics to inform management and resource allocation decisions, collected data on their efforts to address IP crimes that affect public health and safety, or established IP-related performance measures or targets to assess their achievements. Also, Customs and Border Protection’s enforcement of exclusion orders, which stop certain IP-infringing goods from entering the country, has been limited due to certain procedural weaknesses.

The National Intellectual Property Rights Coordination Center, an interagency mechanism created to coordinate federal investigative efforts, has not achieved its mission and staff levels have decreased. Currently, only one agency participates in the center’s activities, which focus on private sector outreach. Agencies have lacked a common understanding of the center’s purpose and agencies’ roles. The center’s upcoming move to a new location presents an opportunity to reconsider its mission.

Key Agencies Involved in IP-Related Enforcement and Their Enforcement Function and Structure

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<th>Function</th>
<th>Seizing</th>
<th>Investigating</th>
<th>Prosecuting</th>
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<tr>
<td>Agency</td>
<td>Customs and Border Protection</td>
<td>Immigration and Customs Enforcement</td>
<td>Federal Bureau of Investigation</td>
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Sources: GAO analysis of agency data; Art Explosion (images).

To view the full product, including the scope and methodology, click on GAO-08-157. For more information, contact Loren Yager at (202) 512-4347 or yagerl@gao.gov.
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<tr>
<td>C3</td>
<td>Cyber Crimes Center</td>
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<td>CBP</td>
<td>Customs and Border Protection</td>
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<td>CCIPS</td>
<td>Computer Crime and Intellectual Property Section</td>
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<td>CHIP</td>
<td>Computer Hacking and Intellectual Property</td>
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<tr>
<td>DHS</td>
<td>Department of Homeland Security</td>
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<td>FBI</td>
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<td>NIPLECC</td>
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<td>STOP</td>
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March 11, 2008

The Honorable George V. Voinovich
Ranking Member
Subcommittee on Oversight of Government Management, the Federal Workforce, and the District of Columbia
Committee on Homeland Security and Governmental Affairs
United States Senate

Dear Senator Voinovich:

Intellectual property (IP) is an important component of the U.S. economy, and the United States is an acknowledged global leader in its creation. The United States grants IP rights through the issue of patents, trademarks, and copyrights, and regards many types of unauthorized IP use—called infringement—as a crime. Examples of IP infringement range from the creation or sale of counterfeit or pirated music and movies to the manufacturing and sale of counterfeit auto parts and pharmaceuticals; the poor quality of some of these goods can be dangerous for consumers. Governments and private companies have cited a recent expansion in IP crimes, noting that criminal networks have increasingly moved into this domain due to high profit potential, ease of market entry, and relatively low risks.1

Federal law enforcement actions against those who manufacture and distribute IP-infringing goods are an important component of U.S. efforts to protect IP creators and owners and American consumers. Federal actions range from seizing IP-infringing goods to prosecuting alleged criminals. Key federal law enforcement agencies that play an active role in enforcing IP rights are the Department of Homeland Security’s (DHS) Customs and Border Protection (CBP) and Immigration and Customs Enforcement (ICE), and the Department of Justice’s (DOJ) Criminal Division, U.S. Attorney’s Offices, and the Federal Bureau of Investigation

The Department of Health and Human Services’ (HHS) Food and Drug Administration (FDA) also plays a role. Several interagency mechanisms exist to coordinate federal IP enforcement efforts, including the National Intellectual Property Law Enforcement Coordination Council (NIPLECC) and the National Intellectual Property Rights Coordination Center.

We reported to you in April 2007 on challenges that CBP faces in carrying out its IP enforcement role to seize IP-infringing goods at U.S. ports of entry and identified certain steps that it could take to improve its efforts. You subsequently asked us to broaden this work and examine efforts undertaken by CBP and other key federal agencies to carry out law enforcement actions against those who commit violations of U.S. IP laws. Specifically, this report: (1) examines federal agencies’ roles, priorities, and resources devoted to IP-related enforcement; (2) evaluates agencies’ IP-related enforcement statistics and achievements; and (3) examines the status of the National Intellectual Property Rights Coordination Center.

Based on our prior work and background research, we determined that CBP, ICE, FBI, and DOJ are the four key law enforcement agencies that play an active role in IP enforcement, and that FDA also plays an important role. To examine the key federal agencies’ roles and priorities for IP-related enforcement, we met with agency officials in their

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\[^2\] We recognize that DOJ’s Criminal Division and the U.S. Attorney’s Offices are not agencies, but these offices work in parallel with the other agencies we reviewed. Thus, DOJ and its entities are discussed in this report as one of the key federal IP enforcement “agencies” for ease of reference. Other federal agencies also play a role in protecting and enforcing IP rights, but we focus in this report on the key federal law enforcement agencies.

\[^3\] FDA’s primary mission is to ensure public health and safety. It has both regulatory and law enforcement authorities and responsibilities. FDA’s Office of Criminal Investigations pursues counterfeit product investigations in furtherance of the agency’s public health mission. Since these counterfeit product cases have an impact on the protection of IP rights, we chose to include FDA in this report.


headquarters and in seven field locations\(^6\) and reviewed strategic plans and other agency documents. To examine agencies’ resources for IP-related enforcement, we obtained information on staff resources, where available. To evaluate IP-related enforcement trends and achievements, we reviewed agency statistics for fiscal years 2001 through 2006, including IP-related seizures, investigations, and prosecutions. We also reviewed agencies’ internal strategic planning documents to determine their priorities, goals, and objectives for IP enforcement and compared them to the types of data agencies collected. To examine the status of the National Intellectual Property Rights Coordination Center, we met with ICE, FBI, DOJ, and FDA officials to discuss its evolution, role, and staffing levels; reviewed agency documents that articulated the center’s purpose; and analyzed congressional appropriators’ conference reports that directed agencies to staff and fund the center. Some of the information we reviewed was considered sensitive for law enforcement purposes, and our report only discusses publicly available information. We obtained private sector views on federal IP enforcement efforts through interviews with representatives from 22 companies and eight industry associations across eight sectors, such as the entertainment, pharmaceutical, and manufacturing industries. We conducted this performance audit from December 2006 through March 2008 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. See appendix I for a more detailed description of our scope and methodology.

### Results in Brief

For the five key federal agencies that play a role in enforcing IP laws, such enforcement is not a top priority, and determining the resources they have devoted to this function is challenging. IP law enforcement actions consist of three primary functions—seizing goods, investigating crimes, and prosecuting alleged criminals. CBP is responsible for seizing IP-infringing goods at the U.S. border, a function that also includes assessing penalties

\(^6\)The field locations we selected were based on the locations we examined in our April 2007 report on CBP (GAO-07-735). For that report, we selected a mix of ports with high and medium import levels, measured by value. For this report, we conducted work at ICE, FBI, and DOJ field offices co-located near these ports to get a sense of the local federal enforcement environment. We did not disclose port identities in our 2007 report for law enforcement reasons; we maintain that confidentiality in this report for the same reasons.
and excluding—or denying entry to—certain types of IP-infringing goods. ICE and FBI share responsibility for investigating those suspected of IP crimes, and FDA investigates counterfeit versions of the products it regulates. DOJ is responsible for prosecuting those accused of committing IP crimes. IP enforcement activities are generally a small part of these agencies’ much broader missions, and, according to agency officials and documents, IP enforcement is not the top priority for these agencies. However, within their IP enforcement activities, these agencies have given enforcement priority to IP crimes that pose risks to public health and safety, such as counterfeit pharmaceuticals, batteries, and car parts.

Determining the federal resources allocated to IP enforcement is challenging because few agency staff are dedicated exclusively to IP enforcement, and only investigative agencies tracked the time spent by non-dedicated staff on IP criminal investigations. The information we obtained shows declining staff resources in some agencies and increases or little change in others. Because agencies’ IP enforcement roles are interdependent, the emphasis one agency places on IP enforcement can affect the actions of others. For example, officials from several investigative agencies’ field offices said their decisions to open IP investigations were influenced in part by the willingness of the local U.S. Attorney’s Office to prosecute certain types of IP enforcement cases.

Federal IP enforcement activity generally increased from fiscal year 2001 through 2006, but agencies have not taken key steps to assess their IP enforcement achievements. Our review of agencies’ enforcement statistics over the 6-year period found that IP enforcement activities generally increased, with fluctuations in activity across fiscal years and type of enforcement action. Specifically, the number of CBP’s seizures have steadily increased, but the domestic value of goods seized varied by fiscal year. However, we found that CBP collected less than 1 percent of penalties assessed during 2001 through 2006. We also found a lack of data on CBP’s exclusion of imports subject to “exclusion orders” and certain procedural issues, such as delays in creating enforcement guidance and minimal electronic targeting in certain cases.7 The number of IP-related criminal investigations that ICE, FBI, and FDA opened each year fluctuated during 2001 through 2006, but the number of arrests,

7CBP is required to exclude goods that are subject to an “exclusion order” issued by the United States International Trade Commission (ITC). The Commission investigates allegations of unfair import practices and issues exclusion orders in cases where it has found unfair import practices. These cases typically involve allegations of patent or trademark infringement.
indictments, and convictions stemming from these investigations generally increased during that time period. The number of IP prosecutions by DOJ for fiscal years 2001 through 2005 hovered around 150 cases before increasing to about 200 cases in fiscal year 2006. Although agencies’ enforcement activities show general increases, agencies have not taken key steps to evaluate their own enforcement trends in ways that would better inform management decisions and resource allocation. For example, agencies have generally not conducted systematic analyses of IP-related enforcement activities, such as by field offices or type of violation pursued. Our analysis of agency data shows that a small number of CBP and DOJ field offices are responsible for the majority of these agencies’ total IP enforcement activity. Further, all the agencies have given priority within their IP enforcement efforts to IP crimes that affect public health and safety, but most have not clearly identified which IP enforcement actions relate to public health and safety or lack data to track their achievements in this area. Finally, agencies have generally not established performance measures or targets to aid them in assessing their IP enforcement achievements and reporting their progress to Congress and interagency coordinating bodies.

The executive branch created the National Intellectual Property Rights Coordination Center to improve and coordinate federal IP enforcement efforts, but the center has not achieved its mission, and staff levels have declined. The center, which began operations in 2000, was set up to be a hub for the collection, analysis, and dissemination to investigative agencies of IP-related complaints from the private sector. However, it got off to a slow start, compounded by the events of September 11, 2001, and the envisioned flow of private sector complaint information never materialized. In addition, participating agencies—FBI, legacy Customs, and ICE—did not reach a common understanding about the center’s purpose and agencies’ roles. Over time its mission shifted and the center began focusing instead on educating the private sector about federal IP enforcement agencies’ efforts. Congressional appropriators expressed support for the center’s creation and mission in various conference reports, which, over time, directed participating agencies to allocate certain appropriated funds to staff and operate the center. However, ICE staff at the center have declined from the levels originally established by

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8The term “legacy Customs” refers to the U.S. Customs Service, which was responsible for collecting revenue in the form of customs duties, taxes, and fees. The center was originally established to be a coordination body between FBI and Customs. Upon the creation of DHS, Customs’ role was shifted to ICE and CBP.
the executive branch, and the FBI and CBP no longer participate in the center. The center is scheduled to move to a new location in early 2008, and ICE officials said they met with the other IP enforcement agencies to invite them to establish or increase their presence there. However, according to some officials from the invited agencies, their future involvement depends in part on clarifying, and perhaps adjusting, the center’s purpose and activities.

To improve agencies’ assessment of their IP enforcement efforts, we make several recommendations to the Attorney General and the Secretaries of Homeland Security and Health and Human Services, including directing their agencies to collect additional data on, and systematically analyze, their enforcement activity and establish related performance measures and targets. To better inform CBP and affected rights holders on the enforcement of exclusion orders, we recommend that the Secretary of Homeland Security direct the CBP Commissioner develop a strategy for addressing identified procedural weaknesses, including collecting additional data to better track its enforcement efforts in this area. To clarify the roles and responsibilities of the National Intellectual Property Rights Coordination Center, we recommend that, in consultation with NIPLECC, the Attorney General and the Secretary of Homeland Security reassess the center’s mission and agencies’ roles in the center.

We provided a draft of this report to DHS, DOJ, and HHS for comment. DHS, CBP, and ICE concurred with our recommendations. DOJ did not comment on our recommendations. HHS said it disagreed with the recommendation that FDA establish performance measures and targets for IP enforcement. Given FDA’s public health and safety mission, we reconsidered the appropriateness of recommending that it establish law enforcement-related performance measures and no longer make this recommendation to FDA. However, because of the importance of understanding and addressing trends in IP violations that affect public health and safety, we added FDA to the recommendation that agencies systematically analyze their IP enforcement activity. In addition, CBP, DOJ, and FDA had certain concerns about portions of our report, which we address at the end of this letter and in appendixes IV, V, and VI. The agencies all made technical comments, which we incorporated as appropriate.
Background

Intellectual property has become a critical component of our country’s economy, accounting for an average of 18 percent of the U.S. gross domestic product from 1998 through 2003. Industries that rely on IP protection—including the aerospace, automotive, computer, pharmaceutical, semiconductor, motion picture, and recording industries—are estimated to have accounted for 26 percent of the annual real gross domestic product growth rate during this period and about 40 percent of U.S. exports of goods and services in 2003 through 2004. Further, they are among the highest-paying employers in the country, representing an estimated 18 million workers or 13 percent of the labor force.

The economic value of IP-protected goods makes them attractive targets for criminal networks. Criminal activities have negative effects for U.S. innovation and investment, the value and reputation of individual companies, and consumers who are put at risk by substandard or dangerous products. Such activity is inherently difficult to measure, but the Organization for Economic Cooperation and Development recently estimated that international trade in counterfeit and pirated products in 2005 could have been up to $200 billion.

According to industry groups, a broad range of IP-protected products are subject to being counterfeited or pirated, from luxury goods and brand name apparel to computer software and digital media to food and medicine. Evidence of counterfeiting in industries whose products have a public health or safety component, such as auto and airline parts; electrical, health, and beauty products; batteries; pharmaceuticals; and infant formula, presents a significant concern. The World Health Organization estimates that as much as 10 percent of medicines sold worldwide are believed to be counterfeit, including essential medicines such as vaccines, antimalarials, and human immunodeficiency virus therapies.

The federal government plays a key role in granting protection for and enforcing IP rights. It grants protection by approving patents or registering...

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It enforces IP rights by taking actions against those accused of theft or misuse. Enforcement actions include both civil and criminal penalties. U.S. laws criminalize certain types of IP violations, primarily copyright and trademark violations, and authorize incarceration or fines. These laws are directed primarily toward those who knowingly produce and distribute IP-infringing goods, rather than those who consume such goods. Although U.S. laws do not treat patent violations as a crime, the federal government does take actions to protect patents and authorizes civil enforcement actions against infringers. See appendix II for a detailed list of the U.S. laws that grant IP protection and the criminal and civil penalties that federal law enforcement agencies are authorized to impose.

Protection is also provided by the U.S. International Trade Commission, which investigates allegations of unfair import practices that commonly involve claims of patent or trademark infringement. For example, in January 2007, the commission issued an “exclusion order” to cease importation of certain types of laminated floor panels that it found infringed on three U.S. patents. Exclusion orders direct CBP to stop certain goods from entering the United States while the order is in effect. The commission is also authorized to take other actions, such as issuing “cease and desist” orders to those engaging in unfair import practices or assessing civil penalties.

These IP rights grant registrants limited exclusive ownership over whatever economic rewards the market may provide for their creations and products. A copyright provides protection for literary and artistic works such as books, musical compositions, computer software, and movies. A copyright is a property right in an original work of authorship that arises automatically upon creation of such a work and belongs, in the first instance, to the author. A patent protects an invention by giving the inventor the right to exclude others from making, using, or selling a new, useful, nonobvious invention during a specific term. Trademarks are words, phrases, logos, or other graphic symbols used by manufacturers or merchants to identify their goods and distinguish them from others. Other types of intellectual property include trade secrets, industrial designs, and geographic indications. Geographic indications are names used to identify products with quality, reputation, or other characteristics attributable to the origin of the product.

Such authority is granted under Section 337 of the Tariff Act of 1930, 19 U.S.C 1337.

Exclusion orders involving patents are generally in effect until the patent expires. Exclusion orders involving trademarks are in effect as long as the trademark is valid and is recognized by the granting agency as being in force.
Congress has supported several interagency mechanisms to coordinate federal IP law enforcement efforts. In 1999, Congress created the interagency NIPLECC as a mechanism to coordinate U.S. law enforcement efforts to protect and enforce IP rights in the United States and abroad.\(^{15}\) Officials from seven federal entities are members of NIPLECC.\(^{16}\) A presidential initiative, called the Strategy Targeting Organized Piracy (STOP), is the council’s strategy, and it articulates five broad goals.\(^{17}\) From 2001, Congress supported the creation of the National Intellectual Property Rights Coordination Center, another interagency mechanism that aims to improve federal IP enforcement and coordinate investigative efforts between ICE and FBI (discussed in detail later in this report).

Multiple Agencies Carry Out IP Enforcement, but Their IP Priorities Vary, and Few Resources Are Dedicated Exclusively to IP Enforcement

For the five key federal agencies with IP enforcement roles, such enforcement is not a top priority for most of them, and determining their resource allocations to IP enforcement is challenging. These agencies’ IP enforcement functions include: (1) seizing IP infringing goods; (2) conducting investigations; and (3) prosecuting alleged violations. The overall aim of U.S. government efforts is to stop trade in counterfeit and pirated goods, and the three functions each present some degree of deterrent. The key law enforcement agencies—CBP, ICE, FBI, and DOJ—have broad missions with many competing responsibilities, and their IP enforcement role is not generally their highest priority, while FDA’s primary mission is to protect public health. We were not able to identify the total resources allocated to IP enforcement across the agencies because few staff are dedicated solely to IP enforcement, and only certain agencies track the time spent on IP criminal investigations by non-dedicated staff who carry out this function. The information we were able

\(^{15}\)In September 1999, Congress authorized NIPLECC (Public Law 106-58). In December 2004, Congress passed legislation to enhance NIPLECC’s mandate (Public Law 108-447). See GAO-07-74.

\(^{16}\)The council’s membership includes officials from: CBP, ICE, DOJ, the Department of Commerce, the U.S. Patent and Trademark Office, the Department of State, and the Office of the U.S. Trade Representative. NIPLECC is required to consult with the Register of Copyrights. DOJ and the U.S. Patent and Trademark Office are co-chairs. The Coordinator for International IP Enforcement (IP Coordinator), a presidential appointee, heads NIPLECC and resides in the Department of Commerce. See GAO-07-74.

\(^{17}\)STOP’s five goals are to: (1) empower American innovators to better protect their rights at home and abroad, (2) increase efforts to seize counterfeit goods at our borders, (3) pursue criminal enterprises involved in piracy and counterfeiting, (4) work closely and creatively with U.S. industry, and (5) aggressively engage our trading partners to join our efforts.
to compile shows declines in IP enforcement resources in several agencies, and fluctuating or growing resource allocations to IP enforcement in others. Because federal IP enforcement roles are interdependent—seizures may launch or contribute to investigations, and investigations may lead to prosecutions—the emphasis placed on enforcement of IP at one agency or field office can impact the IP enforcement efforts of others.

Key Agencies Carry Out Three Primary IP-Related Enforcement Functions

Key federal agencies carry out three IP enforcement functions. Seizing IP infringing goods is primarily performed by CBP. IP-related investigations are performed by agencies located in three different departments. Prosecuting IP crimes is carried out by two different entities within DOJ. Figure 1 identifies the IP enforcement functions and the structure, including the departments and agencies, in which they are performed.

Figure 1: Federal IP Enforcement Functions, the Key Agencies That Execute Them, and the Agencies’ Structures

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Sources: GAO analysis of agency data; Art Explosion (images).

*aThe Department of Justice is not an agency, but given that its Criminal Division and U.S. Attorney's Offices work in parallel with the other agencies we reviewed, DOJ and its entities are described as one of the key federal IP enforcement “agencies” for ease of reference.

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State and local government officials also carry out enforcement of IP laws, and private sector companies and industry associations whose products are counterfeited and pirated often carry out their own enforcement efforts.

We have previously reported on CBP’s efforts to enforce IP rights at the border, including its efforts to target and seize counterfeit goods and assess penalties. See GAO-07-735.
The four key federal law enforcement agencies and FDA have broad missions and many responsibilities, and IP enforcement is not a top priority at most agencies. CBP and ICE address IP enforcement as part of their legacy efforts to combat commercial fraud, but their top mission is securing the homeland. DOJ identifies IP enforcement as one of its top priorities, but FBI does not. FDA’s role is driven by its public health and safety mission, not IP enforcement per se. Regardless of the priority ranking agencies assign to IP enforcement, within their IP enforcement efforts, they have all given priority to IP-related crimes that pose risks to public health and safety. Staff in agency headquarters play a role in setting IP enforcement policies and, at some agencies, carry out certain IP enforcement actions, but most enforcement activity takes place at the field office level. Each field office faces a unique set of challenges in its local environment, balancing IP enforcement efforts with other agency priorities.

Several companies and associations we interviewed remarked that the federal IP enforcement structure is not clear. For example, one association remarked that agency responsibilities are unclear and may overlap, while another said that there is no formal process for referring cases for federal action. This structure was seen as especially challenging for small companies who need federal assistance but lack the resources or expertise to navigate the federal system. Additional information on private sector views about federal IP enforcement is contained in appendix III.

Information is presented below on each agency’s IP enforcement function, the priority assigned to IP enforcement, and the structure within which such enforcement is carried out.

CBP - Seizures, Penalties and Exclusions

- **Function**: CBP is the primary federal agency authorized to seize goods, including IP-infringing goods, upon their arrival in the United States. CBP is also responsible for preventing the entry of goods into the United States that are subject to exclusion orders and assesses penalties against IP infringers when warranted.
Priorities: CBP’s primary mission is to protect the homeland. CBP is also responsible for carrying out its legacy Customs functions, including trade enforcement. CBP has identified six Priority Trade Issues, one of which is IP enforcement. Within its IP enforcement efforts, CBP gives priority to large value seizures and violations that affect public health and safety or economic security or that have ties to terrorist activity.

Structure: CBP’s Office of International Trade develops IP enforcement policies and plans, develops national instructions for targeting shipments suspected of carrying IP-infringing goods, writes guidance for assessing penalties and enforcing exclusion orders, and maintains data on IP-related seizures. The Office of Field Operations oversees implementation of these policies and procedures at 325 U.S. ports of entry. While much of CBP’s IP enforcement activity is carried out by the ports, headquarters staff play an integral role in supporting those efforts, including providing policy and guidance on enforcement priorities and developing systems and technologies to enhance enforcement.

Function: ICE conducts investigations of IP-related criminal activity, including infringement of trademark and copyright law.

Priorities: ICE’s primary mission is to protect the homeland. It is also responsible for combating commercial fraud, which includes IP enforcement. ICE’s interim agency-wide strategic plan and its plan for commercial fraud are law enforcement sensitive and not available to the public. However, according to ICE officials, the top priorities within commercial fraud enforcement are public health and safety violations and IP infringement.

Structure: Within ICE’s Office of Investigations, the Critical Infrastructure and Fraud Division develops the agency’s IP policies and

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20 As of fiscal year 2006, CBP’s Priority Trade Issues included agriculture, antidumping and countervailing duties, IP rights, penalties, revenue, and textiles and wearing apparel.

21 We reported in April 2007 that a lack of integration between these two offices impedes CBP’s ability to improve its IP enforcement efforts. See GAO-07-735.
oversees its IP enforcement efforts. The division’s IP responsibilities are handled by the Branch for Commercial Fraud and Intellectual Property Rights, which also houses the National Intellectual Property Rights Coordination Center. Although the center is officially an interagency coordination body, it plays a lead role in developing and carrying out ICE’s IP enforcement policies. In addition, ICE has a Cyber Crimes Center that focuses on Internet-based crimes, including IP piracy, and provides referrals and investigative assistance to ICE’s field offices. IP investigations are carried out by agents located in about 100 U.S. cities, organized under ICE’s 26 field offices.

**FBI Criminal Investigations**

- **Function:** FBI conducts investigations of IP-related criminal activity, including infringement of trademark and copyright law, as well as theft of trade secrets.

- **Priorities:** The FBI’s principal mission is to investigate criminal activity and defend the security of the United States. It has identified 10 priority enforcement areas, including cyber crime. IP enforcement is included in the cyber crime area, but it is ranked 5th out of FBI’s 6 cyber crime

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22The division also investigates immigration violations, customs fraud, and cases involving worksite enforcement and human smuggling.

23The Cyber Crimes Center is often referred to by the acronym “C3.”

24As of 2006, FBI had 10 priority enforcement areas. The first 8 in order of importance are to: (1) protect the U.S. from terrorist attack; (2) protect the U.S. against foreign intelligence operations and espionage; (3) protect the U.S. against cyber-based attacks and high-technology crimes; (4) combat public corruption at all levels; (5) protect civil rights; (6) combat transnational and national criminal organizations and enterprises; (7) combat major white collar crime; and (8) combat significant violent crime. In addition, FBI aims to (9) support federal, state, local, and international partners; and (10) upgrade technology to successfully perform FBI’s mission.
priorities.\textsuperscript{25} Within its IP enforcement efforts, FBI’s priorities are, in order, trade secret theft, copyright infringement, trademark infringement, and signal theft, and one of FBI’s IP enforcement goals is for its field offices to initiate IP investigations that affect public health and safety.

- **Structure**: FBI’s Cyber Division oversees the agency’s IP enforcement efforts even though not all of its IP investigations are cyber-related.\textsuperscript{26} A single unit within the Cyber Division, called the Cyber Crime Fraud Unit, has operational and management oversight for all of FBI’s cyber crime activities. IP-related investigations are primarily carried out in FBI’s 56 field offices.

### FDA Criminal Investigations

- **Function**: FDA investigates illegal activity pertaining to food, drugs, medical devices, and other products because of the impact on public health.\textsuperscript{27}

- **Priorities**: FDA’s primary mission is to protect public health by assuring the safety, efficacy, and security of human and veterinary drugs, the food supply, medical devices, and other products. IP enforcement is not part of FDA’s mission or its enforcement priorities; however, FDA carries out IP-related enforcement actions in fulfilling its mission to protect public health and safety, such as investigating criminals that traffic in counterfeit pharmaceuticals.

\textsuperscript{25}Cyber Division’s six priorities are, in order of importance: (1) computer intrusions involving counterterrorism, (2) computer intrusions involving counterintelligence, (3) other computer intrusions, (4) innocent images (child pornography), (5) IP enforcement, and (6) Internet fraud. In April 2006, the Cyber Division lowered the priority of IP enforcement to 5th rank and elevated the priority of child pornography to 4th rank. Despite this decrease in stated priority, Cyber Division officials said that IP investigations remain a major focus of their program, particularly investigations targeting health and safety issues.

\textsuperscript{26}This division also conducts investigations of computer intrusions and child pornography.

\textsuperscript{27}The Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.) provides legal authority for FDA to conduct counterfeit product investigations and enforcement actions. In addition, FDA brings charges under the statute that prohibits trafficking in counterfeit goods (18 U.S.C. 2320).
• **Structure**: FDA’s Office of Regulatory Affairs, in collaboration with other agency components, carries out the agency’s enforcement activities. This office houses, among other entities, FDA’s Office of Criminal Investigations and the Division of Import Operations. The Office of Criminal Investigations, with six field offices and presence in 25 U.S. cities, has the primary responsibility for all criminal investigations conducted by the FDA. The Division of Import Operations provides guidance on the agency’s import policy to FDA field staff, including at numerous ports around the country. FDA field staff that discover suspected counterfeit imports of products that are regulated by FDA would refer these to the Office of Criminal Investigations for further action. In addition, Office of Regulatory Affairs laboratories play a role by analyzing samples of suspected counterfeit products.

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**DOJ - Prosecutions**

• **Function**: DOJ prosecutes IP cases referred from ICE, FBI, and FDA, as well as from private sector representatives and other sources.

• **Priorities**: According to DOJ officials and documents, IP enforcement is one of the department’s highest priorities. In March 2004, the Attorney General announced the creation of a DOJ Task Force on Intellectual Property, with a mission of identifying ways to strengthen the department’s IP enforcement efforts. The Task Force produced 31 recommendations for improving IP enforcement and provided a progress report on those recommendations in its 2006 report. The Task Force made numerous short- and long-term recommendations, including increasing the number of DOJ prosecutors and FBI agents that focus on computer crime and IP cases and prosecuting IP cases involving a threat to public health and safety. In addition, DOJ developed an internal IP enforcement strategy for 2007 with six strategic objectives designed to help it meets its larger goal of reducing IP theft. DOJ shared this document with us, but its contents are for official government use only.

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- **Structure**: DOJ's IP enforcement is carried out primarily by the 94 U.S. Attorney's Offices located throughout the country as well as its Criminal Division's Computer Crime and Intellectual Property Section (CCIPS). Under DOJ's Computer Hacking and Intellectual Property (CHIP) program, each U.S. Attorney's Office has one CHIP coordinator who is trained in prosecuting IP enforcement cases. In addition, 25 U.S. Attorney's Offices have CHIP units, usually comprised of 2 or more attorneys (a few units have as many as 8 attorneys), who focus solely on prosecuting computer hacking or IP crimes. IP crimes prosecuted by the U.S. Attorney's Office are not limited to CHIP units, but may be prosecuted as part of a larger case, such as one involving organized crime. CCIPS, located in DOJ headquarters, is responsible for supporting IP prosecutions by U.S. Attorney's Offices, as well as prosecuting their own cases. CCIPS is also responsible for developing DOJ's overall IP enforcement strategy and coordinating among U.S. and foreign law enforcement officials on domestic and international cases of IP theft.

### Determining the Total Resources Allocated to IP-Related Enforcement Is Challenging

Determining the total resources that agencies have allocated to IP enforcement is challenging because agencies have few staff exclusively dedicated to IP enforcement, and only the agencies that conduct criminal investigations estimated time spent on this activity. Most agencies have some headquarters staff exclusively dedicated to IP enforcement. However, staff in the field, where most IP enforcement activity occurs, are generally not dedicated exclusively to IP enforcement. The information we were able to compile shows declines in IP enforcement resources in some agencies and fluctuating or growing resource allocations to IP enforcement in others. Agencies’ ability to allocate staff to IP enforcement is affected by not only the priority they assign to this function but also their overall resource situation. Some agencies have faced resource challenges in recent years.

Private sector representatives we interviewed across various sectors expressed concern about the federal government’s ability to carry out IP enforcement due, in part, to a lack of resources. While several companies said that federal IP enforcement efforts have increased, 14, or nearly half,

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29Under the CHIP program, prosecutors are assigned four areas of responsibility: prosecuting computer crime and IP offenses; serving as a technical advisor for other prosecutors and law enforcement agents; assisting other CHIP coordinators in multi-district investigations; and providing training and community outreach regarding computer-related issues.
of the representatives we contacted said there is a shortage of resources to carry out IP enforcement. Appendix III provides further detail on private sector views.

Information on each agency’s resources for IP-related enforcement are detailed below.

CBP - Seizures, Penalties, and Exclusions

Various types of CBP staff play a role in IP enforcement. The only staff that are dedicated exclusively to IP enforcement are international trade specialists, attorneys, and paralegals assigned to the Office of International Trade, and their numbers have fluctuated over time. International Trade Specialists are responsible for performing nationwide targeting for all CBP ports of incoming shipments suspected of carrying IP-infringing goods and for analyzing IP seizure data. The number of international trade specialists remained relatively flat from fiscal year 2003 through 2006, at about 11, before increasing to 17 in 2007. However, the number of these specialists that were performing targeting in 2003 through 2006 actually declined.\textsuperscript{30} Attorneys are responsible for advising ports on how to carry out CBP’s IP enforcement authorities and have sole responsibility for developing exclusion order enforcement guidance, a highly complex and labor intensive task. The number of attorneys devoted to IP enforcement declined from 11 in 2003 to 9 in 2006 and remains at that level. Other CBP staff perform IP enforcement activities, but are not exclusively dedicated to it; CBP does not track the amount of time these staff spend on IP enforcement.\textsuperscript{31} In addition, within the Office of

\textsuperscript{30}During 2003 through 2005, all 11 International Trade Specialists were assigned to headquarters but worked out of CBP’s Strategic Trade Center in Los Angeles and a satellite office in San Francisco. In 2006, the number of staff performing targeting in the field was reduced to 8. Three positions were shifted to headquarters, and the staff in these positions were not performing targeting. As of July 2007, CBP increased the number of specialists in the field to 12 and the number in headquarters to 5. The increase in the field enabled CBP to reduce the number of industries for which each specialist is responsible.

\textsuperscript{31}CBP officers are responsible for examining shipments with suspected counterfeit goods, but one of their primary focus is screening cargo for weapons of mass destruction. Import specialists are responsible for applying duties to imports and develop expertise in certain goods, including a determination of whether imports are counterfeit. Fines, Penalties, and Forfeiture officers are responsible for assessing penalties against importers that violate U.S. trade laws, as well as those that traffic in counterfeit goods.
International Trade, CBP auditors perform targeted audits on selected companies to assess their internal controls for preventing the importation of IP-infringing goods. CBP does track hours spent on IP audits. As of December 2007, CBP reported that slight over 14 “man years” have been charged to IP audits since fiscal year 2005, when such audits were initiated.

CBP staff that carry out the agency’s IP enforcement activities operate in an environment that is plagued by staffing challenges, including staffing shortages, difficulty hiring and retaining staff, and fatigue among its workforce. For example, in November 2007, we reported that CBP estimates it may need several thousand more CBP officers to operate its ports of entry. In April 2007, we also reported that staff resources at CBP for customs revenue functions have declined since the formation of DHS.

Among the agencies that conduct criminal investigations, only ICE has staff dedicated exclusively to IP enforcement. These include ICE staff assigned to the National Intellectual Property Rights Coordination Center and a commercial fraud team in one of its field offices that focuses solely on IP enforcement. As discussed later in this report, the number of ICE staff assigned to the center declined from 15 in 2004 to 8 in 2007. Neither FBI nor FDA have any staff dedicated exclusively to IP enforcement. A senior FBI Cyber Division official said the size of FBI’s IP enforcement effort is small relative to other FBI efforts and has limited resources.

However, ICE, FBI, and FDA all track the amount of time that their investigators spend on IP-related investigations (see fig. 2). By converting ICE and FDA investigative hours to full-time-equivalent (FTE) positions, we used the formulas provided by the agencies.

34ICE and FDA use different calculations to compute their FTE equivalents. We used the formulas provided by the agencies.
and using a similar measure (average on board) for FBI, we determined that ICE spent an average of 154 FTEs on IP enforcement during 2001 through 2006, while FBI averaged 53 agents on board for IP enforcement, and FDA spent an average of 16 FTEs. ICE investigative resources spent on IP enforcement increased from 2001 to 2003 before falling off, while the estimated number of investigator FTEs spent on IP cases at FBI and FDA experienced little change over the 6-year period.

**Figure 2: Estimated Number of Investigative Resources Spent on IP-Related Investigations by ICE, FBI, and FDA, Fiscal Years 2001-2006**

Investigative resources spent on IP-related enforcement

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Source: GAO analysis of agency data.

Note: ICE and FDA capture the number of investigative case hours worked and provided formulas for converting to FTEs. FBI captures the average agents on board that worked IP investigations, which we report in this figure as FTEs. FDA did not begin to collect data on the number of investigative case hours until fiscal year 2003.
DOJ dedicates staff to IP enforcement in headquarters and within its U.S. Attorney’s Offices. The number of staff dedicated to IP enforcement has grown in recent years. For example, DOJ’s CHIP units, first created in February 2000, grew from 13 units as of 2002 to 25 units as of 2007. Most of the CHIP units have approximately two or more attorneys who focus on prosecuting IP and high-technology crimes, with as many as eight in at least one of the units. As the number of units has grown, so has the number of attorneys assigned to working IP cases. As of July 2007, DOJ had 101 Assistant U.S. Attorneys assigned to CHIP units. Another 122 Assistant U.S. Attorneys have been specially trained to prosecute computer crime and IP offenses, with at least one such CHIP prosecutor located in every U.S. Attorney’s Office. DOJ began tracking the time attorneys spend on IP enforcement in May 2006, but we did not collect this data.\footnote{DOJ’s relatively recent data collection effort did not allow us to track attorney time spent on IP enforcement over time, as we have done for other agencies.}

In addition, according to DOJ, it had 14 attorneys working on IP enforcement in its CCIPS. Despite having these dedicated and trained staff, however, officials from the U.S. Attorney’s Offices we visited noted that, over the past few years, their offices have experienced high turnover and have been generally understaffed, with vacant positions left unfilled.

Agency Enforcement Roles and Actions Are Often Interdependent

Given the interdependent nature of federal IP enforcement and the central role played by the field offices, the emphasis placed on IP enforcement at one location can affect the IP enforcement efforts of others. For example, investigative agency officials at some locations we visited said that their decisions about beginning or continuing an IP-related investigation were influenced by the willingness of the local U.S. Attorney’s Office to prosecute the case. Some field office officials we interviewed stated that local U.S. Attorney’s Offices set minimum value thresholds for taking IP cases, in part because the U.S. Attorney’s Offices also have limited resources. However, officials at the U.S. Attorney’s Offices we visited said that they did not have specific thresholds for IP prosecutions, particularly when it comes to public health and safety, and that they evaluate cases on their individual merits. Similarly, the degree to which an ICE field office...
can accept and work on IP enforcement referrals from CBP may depend on the field office’s other priorities, such as money laundering or smuggling enforcement. Officials at most of the agencies noted other factors that influence their IP-related enforcement decisions, including the number or value of items seized, the health or safety impacts of the crime, and the organizational structure of the entities involved.

Federal IP enforcement activity generally increased from fiscal year 2001 through 2006; however, most agencies have not taken key steps to assess their achievements. Specifically, most agencies have not: (1) conducted systematic analyses of their IP enforcement data to inform management and resource allocation decisions, (2) clearly identified which of their efforts relate to a key IP enforcement area—IP crimes that affect public health and safety—nor collected data to track these efforts, and (3) established performance measures or targets to assess their achievements and report to Congress and others.

Our review of agency statistics for fiscal years 2001 through 2006 indicated that IP enforcement actions generally increased over the period, with some fluctuations in activity. The number of CBP seizure actions and the value of such seizures has increased significantly. Investigative agencies’ enforcement outcomes—arrests, indictments, and convictions—also increased during the time period. The number of DOJ prosecutions hovered around 150 cases per year during fiscal years 2001 to 2005 before increasing to about 200 cases in fiscal year 2006, with the number of defendants charged with IP crimes fluctuating.

CBP’s primary IP enforcement efforts involve seizing IP-infringing goods that individuals attempt to import through U.S. ports of entry. In April 2007, we reported that the total number of CBP’s seizure actions has grown since fiscal year 2001, nearly doubling from fiscal years 2005 to 2006; however, most of these actions involved numerous small-value seizures made from air-based modes of transport while significantly fewer seizure actions have been made from sea- or land-based modes of transport.36 We reported in 2007 that CBP officials said they believed the trend reflects growing Internet sales and the ability of manufacturers to directly ship their merchandise to consumers through mail and express

36GAO-07-735.
consignment. At that time, some CBP officials stated that this trend may reflect a shift in smuggling techniques toward the use of multiple small packages rather than large shipments in cargo containers, possibly to reduce the chance of detection. See figure 3 for trends in the number of CBP seizure actions and estimated domestic values.\[37\]

Figure 3: Trends in the Number of IP Seizure Actions and Estimated Domestic Values of Seizures by CBP, Fiscal Years 2001-2006

After CBP seizes the counterfeit goods, it may also assess penalties that result in monetary fines imposed against the violator. CBP officials reported that processing penalty cases is resource-intensive, but noted that few penalties are collected and such enforcement has little deterrent effect. We found that less than 1 percent of the penalty amounts assessed for IP violations in each fiscal year were collected. See table 1 for IP-related penalties assessed and collected in each fiscal year from 2001 through 2006. Various factors contribute to CBP’s limited collection rates on IP penalties, including petitions for mitigation or dismissal by the

\[37\]Domestic value is calculated as the landed cost plus profit (the cost of the merchandise when last purchased, plus all duties, fees, broker’s charges, profit, unlading charges, and U.S. freight charges to bring the good to the importer’s premises), a value generally lower than the price at which the goods might sell to the final consumer.
CBP’s Enforcement of Exclusion Orders Has Been Limited

CBP does not maintain statistics on all of its exclusion order activities, but available information indicates that its exclusion activities have declined, in part due to procedural weaknesses. While the U.S. International Trade Commission issues relatively few exclusion orders each year, these orders can affect large volumes of trade, according to CBP officials. As of July 2007, 66 exclusion orders were in effect, according to CBP. CBP takes two basic steps to enforce these orders: (1) CBP posts written guidance, called

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Table 1: Dollar Value of IP Penalty Amounts Assessed and Collected by CBP, Fiscal Years 2001-2006

<table>
<thead>
<tr>
<th></th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total penalty amount assessed</td>
<td>$52.0</td>
<td>$65.0</td>
<td>$45.0</td>
<td>$442.9</td>
<td>$423.9</td>
<td>$136.6</td>
</tr>
<tr>
<td>Total penalty amount collected</td>
<td>$0.5</td>
<td>$0.3</td>
<td>$0.4</td>
<td>$0.5</td>
<td>$0.4</td>
<td>$0.6</td>
</tr>
<tr>
<td>Percent collected</td>
<td>0.90</td>
<td>0.48</td>
<td>0.91</td>
<td>0.11</td>
<td>0.10</td>
<td>0.45</td>
</tr>
</tbody>
</table>

Source: GAO analysis of CBP data.

Note: Penalty data are based on penalties assessed under 19 U.S.C. 1526(f). All data presented are based on statistics available as of January 2007. Penalty amounts assessed in one fiscal year may not be collected until the following fiscal year, therefore, there is not a direct relationship between amounts assessed and collected in a given fiscal year. CBP officials said that the amount collected may change on different dates that data are run for open penalty cases that are still being processed; however, officials noted that future adjustments are unlikely to significantly change the disparity between penalty amounts assessed and collected. CBP officials said that they use the same type of collection calculation to report penalty statistics to Congress.

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38 CBP officials said that many violators petition to have a penalty mitigated or dismissed, and these actions often reduce the amount of the penalty that CBP collects. They said that the statutory fines are large, and when a collection action goes to court, DOJ attorneys who prosecute the government’s case are reluctant to pursue the case because they view the penalty amounts as excessive. One agency official explained that some penalties are dismissed as a result of the case going to criminal prosecution, in which the U.S. Attorney negotiates to have a penalty dropped in exchange for information or other evidence that will support the criminal case. Also, the deceptive nature of counterfeit importation makes it difficult for CBP to track violators and enforce penalties.

39 CBP is required to exclude from entry to the United States goods that are subject to exclusion orders issued by the U.S. International Trade Commission. Such orders are issued when the commission has found unfair import practices, typically involving patent or trademark infringement.
Trade Alerts, to its intranet to inform ports about new orders, and (2) it creates electronic targeting instructions that alert ports about incoming shipments that need to be examined for potential infringing goods related to the order. When its exams identify goods that should be excluded, CBP does not allow the goods to enter the country and issues a notice of exclusion to the importer. According to CBP officials, CBP does not maintain data on the number of exclusion notices, either in total or by order, nor does it alert the rights holder of the exclusion. However, CBP does maintain data on the total number of exclusion order exams it conducts and the number of times these exams reveal any IP discrepancies. As shown in figure 4, the number of exclusion order exams have declined since fiscal year 2002, and a very small number of discrepancies have been found. CBP explained that the decrease in exams from fiscal years 2002 to 2004 was due to the termination of targeting for one exclusion order that had been generating most of the exams.

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40 Trade Alerts are developed by attorneys in CBP’s Office of International Trade, based on U.S. International Trade Commission documents related to the exclusion order, and explain how to identify the goods that are to be excluded.

41 According to CBP, most of the IP discrepancies it found in the course of conducting exclusion order exams were not violations of the order, but were other types of IP discrepancies, such as trademark violations, that it found during the exam.

42 CBP was unable to provide similar data for 2001.

43 CBP officials said that, in terminating its targeting, CBP reviewed current use of the patented technology—a process for creating acid-wash jeans—covered by the order as well as the results of its exams, which CBP officials said uncovered no violations of the order.
CBP’s limited and declining enforcement of exclusion orders has been of concern to certain private sector representatives, notably the companies that have sought such orders or the attorneys that represent them. Representatives said companies spend millions of dollars in legal fees to win a U.S. International Trade Commission ruling for their products, but that the effectiveness of the ruling is weakened by poor enforcement at CBP. Private sector representatives also stated that CBP’s enforcement of the orders is not transparent because CBP does not notify companies of any exclusions that have occurred, impeding their ability to follow through on the matter. This differs from CBP’s practices when it detains or seizes IP-infringing goods: CBP notifies both the importer and IP rights owner of such detentions or seizures.\(^4\) CBP officials said the agency does not have a regulation to permit the notification of exclusions to affected rights holders.

\(^4\)Under 19 U.S.C. 1499 and Customs regulation 19 C.F.R. 12.39, CBP notifies importers and other interested parties when it detains goods for examination. In cases involving IP infringement, CBP notifies the affected rights holder of the detention. In addition, CBP also notifies the rights holder when it seizes IP-infringing goods that bear counterfeit trademarks (under 19 C.F.R. 133.21(c)) or goods seized as piratical (under 19 C.F.R. 133.42(d)).
owners, and they did not know whether CBP had legal authority under the relevant statute to make such notifications.

We found several procedural weaknesses in CBP’s exclusion order enforcement, including a lack of intranet Trade Alerts for about half of the orders currently in force, delays in posting Trade Alerts to its intranet, minimal use of electronic targeting, and no procedures for updating Trade Alerts when the status of exclusion orders changes or expires. The effect of these weaknesses has been to limit or delay the degree to which exclusion orders are enforced; details are provided below.

- CBP does not have Trade Alerts on its intranet for all orders currently in effect and lacks information to develop Trade Alerts for some orders. Of the 66 orders in effect as of July 2007, CBP had posted Trade Alerts to its internal website for 24 of them and was developing such guidance for 5 others. CBP said it had paper records for 15 older orders that it had not yet converted to Trade Alerts due to limited resources, but lacked records for enforcing most of these remaining orders.\footnote{When it provided this data to us, CBP stated that enforcement activity based on exclusion orders can vary, depending on the nature of trade in the product covered by the order. These orders may result in a flurry of enforcement activity for a few weeks, months, or years, depending on trade trends. For example, the order may cover a product for which demand is high for a short period of time. However, orders may continue to be legally in effect after trade in the product has ceased.}

- Although CBP officials said the agency is required to enforce the orders from the date they are issued, we found that CBP’s enforcement may be considerably delayed. According to CBP officials, this is because CBP must review and interpret large amounts of complex information generated by the administrative process, but only two attorneys at CBP are presently qualified to carry out this review.\footnote{According to CBP officials, issuing exclusion orders is a multi-step process that involves, among other steps, coordinating with the U.S. International Trade Commission prior to an order’s issuance, making legal and other determinations after an order issues, often in consultation with the company filing for an order, and coordinating enforcement efforts within CBP after instructions have been crafted.} We determined that it took CBP more than 60 days to post Trade Alerts for 14 of 18 orders for which it could provide such data.\footnote{CBP provided exclusion order issue and Trade Alert dates for the 29 orders it said it was enforcing as of July 2007. However, the Trade Alert date it provided for 11 orders was not the date that the Alert was originally posted to its Web site, so we removed these orders from our analysis. The time lag for posting the Trade Alerts we analyzed ranged from 1 week to slightly over 10 months.} According to CBP officials, work to establish...
the intranet platform for IP issues began in 2003, but CBP did not have the capability to actually begin posting Trade Alerts to its Web site until April of 2004. Prior to that date, text-only Alerts were published to an internal electronic bulletin board that housed them for 90-day renewable periods.

- CBP develops targeting instructions for most, but not all, of the exclusion orders it receives. Of 10 randomly selected orders for which CBP had posted Trade Alerts as of July 2007, we found that it had developed targeting instructions for only 4.\(^\text{48}\) Also, although CBP officials said that the agency is to enforce exclusion orders until they expire, we found that its actual targeting instructions for an order may expire far sooner. CBP officials said that targeting instructions that have not generated any exams or found any IP violations after 90 days are removed from CBP’s targeting system. CBP provided data on the number of exclusion orders for which it had targeting instructions in place in each of fiscal years 2003 through 2006. The number of orders with targeting instructions dropped from 25 in fiscal year 2003 to 10 in fiscal year 2006—far fewer than the number of orders in force at that time.\(^\text{49}\)

- CBP has no process for ensuring that its Trade Alerts are adjusted to reflect changes in the status of exclusion orders. For example, CBP initially provided data to indicate that it had issued Trade Alerts for 29 orders, but we determined that 5 of the Trade Alerts were for orders that had expired or been rescinded. CBP concurred with our findings and said it would adjust its Trade Alerts accordingly.

The number of criminal IP enforcement cases opened annually by ICE, FBI, and FDA during fiscal years 2001 through 2006 have fluctuated, but the enforcement outcomes—arrests, indictments, and convictions—from those cases grew during that same time period. As shown in figure 5, ICE opened the most IP cases each year, averaging 445 cases per fiscal year.

\(^{48}\)CBP said that two of the orders for which it performed no targeting involved products that typically enter the United States via express mail consignment (e.g., Federal Express or similar providers), a mode of transport for which its electronic targeting is not used. For two other orders, it said that targeting action by CBP was not required due to the lack of import activity. CBP provided no explanation for its lack of targeting for the remaining three orders.

\(^{49}\)The specific orders for which instructions existed varied during this time period, with instructions for older orders being removed and instructions for new orders being added. Of the 25 orders for which targeting instructions existed in 2003, 14 were still in effect as of February 2008. However, only one of these orders was continuously enforced from fiscal years 2003 through 2006.
compared to FBI’s and FDA’s average of 306 and 39 cases per fiscal year, respectively. The number of IP cases that ICE and FBI opened during the period fluctuated, with the number of ICE cases lower in 2006 than in 2001 and the number of FBI cases in 2006 about the same as their 2001 level. In general, the number of FDA cases grew during this time period.

Despite the fluctuations in numbers of IP cases by the two major investigative agencies, the number of arrests, indictments, and convictions stemming from ICE and FBI investigations of IP-related crimes generally increased for fiscal years 2001 through 2006 (see fig. 6), as they did for FDA. For some enforcement actions, the agencies’ investigative activity showed fairly steady growth. For other actions, investigative activity

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50 The number of FDA’s cases opened is much lower than ICE’s and FBI’s number of cases because of FDA’s narrow jurisdiction.
peaked in fiscal year 2004, but had levels in 2006 that were still well above their 2001 levels.  

![Figure 6: Number of Arrests, Indictments, and Convictions by FBI, ICE, and FDA, Fiscal Years 2001-2006](image)

As figure 6 illustrates, each agency’s enforcement activity generally increased from fiscal year 2001 to 2006; however, activity levels within and across agencies varied over the 6-year period.

DOJ’s IP Enforcement Has Generally Increased

DOJ tracks its IP enforcement activity in terms of the number of cases filed, the number of defendants in cases filed, and the number of defendants convicted. While the number of IP cases filed by DOJ fluctuated around 150 from fiscal years 2001 through 2005, the number of cases grew to 204 in fiscal year 2006 (see fig. 7).

51The data we report for ICE differ from data that ICE has provided in the past to NIPLECC’s IP Coordinator for inclusion in the IP Coordinator’s quarterly updates on federal IP enforcement efforts (see www.stopfakes.gov). In many instances, the numbers we report are lower. We discussed these differences with ICE, which explained that enforcement data pulled from its systems may vary each time the data are requested because its systems are continually updated. More importantly, the parameters ICE used to create the data for the IP Coordinator differed somewhat from the parameters that ICE advised us to use. We believe our parameters provide a more accurate representation of ICE’s IP enforcement activities. Data on ICE’s arrests, indictments, and convictions were not included in the IP Coordinator’s quarterly update for the fourth quarter of 2007.
Figure 7: Number of IP-Related Cases Filed by DOJ, Fiscal Years 2001-2006

Number of cases filed

<table>
<thead>
<tr>
<th>Fiscal year</th>
<th>Number of cases filed</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
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</tr>
<tr>
<td>2002</td>
<td>50</td>
</tr>
<tr>
<td>2003</td>
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</tr>
<tr>
<td>2004</td>
<td>150</td>
</tr>
<tr>
<td>2005</td>
<td>200</td>
</tr>
<tr>
<td>2006</td>
<td>250</td>
</tr>
</tbody>
</table>

Source: GAO analysis of DOJ data.

Note: IP statistics include charges for the following criminal statutes: Title 17 U.S.C. 506, 1201, 1202, 1203, 1204, and 1205; Title 18 U.S.C. 1831, 1832, 2318, 2319, 2319A, 2319B, and 2320; Title 47 U.S.C. 553, 605.

The results of IP-related cases that DOJ filed during fiscal years 2001 through 2006 varied. Table 2 shows that for fiscal years 2001 through 2006, DOJ received referrals for 3,548 defendants in IP matters from the investigative agencies and filed charges against a total of 1,523 defendants. During this period, a total of 891 defendants were convicted and 373 received prison sentences. According to DOJ officials, the data for the number of IP-related defendants referred to federal prosecutors from investigative agencies should be considered independent of the data for defendants charged with IP violations. Additionally, the difference

52Not all persons who are investigated for, or charged with, IP crimes are convicted and sentenced for those crimes, although they still may receive prison sentences. According to DOJ officials, persons who are investigated for the commission of both IP crimes and related crimes that carry potentially lengthier sentences may receive convictions and sentences for the more serious crimes in lieu of IP convictions. In such a case, an IP charge may be dismissed pursuant to plea negotiations, or it may not be filed at all. Additionally, if an IP offense is charged only as a conspiracy, DOJ states that the conspiracy charge will generally not be recorded as an IP charge or an IP conviction in DOJ’s database for prosecutions by U.S. Attorney’s Offices.
between the number of referred IP defendants and the number of defendants charged with IP offenses in a given year, or period of years, may be explained in part by the fact that IP suspects may never be charged with IP offenses because they are instead charged with crimes carrying higher statutory maximum sentences, or because the IP charges are dismissed pursuant to plea agreements to more serious charges.\textsuperscript{53} We found that over the 6-year period of our review, about 17 percent of the total number of defendants received prison sentences of more than 3 years, while about 45 percent were sentenced to imprisonment of 12 months or less.\textsuperscript{54}

\begin{table}[h]
\centering
\caption{DOJ's IP Crime Sentencing Outcomes, Fiscal Years 2001 - 2006}
\begin{tabular}{lcccc}
\hline
Fiscal year & Number of IP-related defendants referred from investigative agencies\textsuperscript{a} & Number of defendants charged with IP-related violations\textsuperscript{a} & Number of defendants convicted of IP-related crimes\textsuperscript{b} & Number of defendants imprisoned for IP-related crimes \\
\hline
2001 & 514 & 200 & 153 & 52 \\
2002 & 497 & 215 & 165 & 65 \\
2003 & 563 & 246 & 141 & 58 \\
2004 & 565 & 177 & 134 & 66 \\
2005 & 724 & 346 & 122 & 53 \\
2006 & 685 & 339 & 176 & 79 \\
\hline
Total & 3,548 & 1,523 & 891 & 373 \\
\hline
\end{tabular}
\end{table}

\textsuperscript{a}According to DOJ officials, the data for the number of IP-related defendants referred to federal prosecutors from investigative agencies should be considered independent of the data for defendants charged with IP violations. The difference between the number of referred IP defendants and the number of defendants charged with IP offenses in a given year, or period of years, is due, in part, to the fact that IP suspects may never be charged with IP offenses because they are instead charged with crimes carrying higher statutory maximum sentences, or because the IP charges are dismissed pursuant to plea agreements to more serious charges.

\textsuperscript{b}The IP statutes specify statutory maximum sentences for a first offense of 3 to 5 years for copyright violations, and up to 10 years for both trademark and trade secret violations.

\textsuperscript{54}According to DOJ, defendants are sentenced pursuant to the U.S. Sentencing Guidelines, and for most IP offenses are determined based on offense level 8 (0-6 months) for most IP offenses, with offense-level enhancements for, among other things, infringement amount, manufacturing or importation, and conscious or reckless risk of serious bodily injury.
Agencies have not taken key steps to assess IP enforcement achievements. Specifically, most agencies have not (1) conducted systematic analysis of their enforcement activity, (2) clearly identified which of their efforts relate to a key IP enforcement area—IP crimes that affect public health and safety—nor collected data to track these efforts, or (3) set performance measures or targets for carrying out IP enforcement. These steps are an important part of agencies’ ability to effectively plan and assess their performance and report to Congress and others.

Although agencies’ statistics show general increases in the level of seizures, investigations, and prosecutions, they have not taken steps to understand the drivers behind these increases in ways that could better inform management and resource allocation decisions. For example, while all the agencies reported using IP enforcement statistics to compare outputs from one year to the next, our discussions with agency officials revealed that little has been done to systematically examine enforcement statistics. Such analysis might include looking at field offices or regions with higher or lower levels of activity to identify effective enforcement practices and inform resource allocation decisions. It might also include identifying the types of IP crimes that agency staff are enforcing to understand criminal activity and help focus enforcement efforts.

Agencies are already collecting some data that could be used to examine enforcement efforts more systematically. In April 2007, we reported that CBP has not analyzed variations in its IP enforcement activity by port or conducted analysis of ports’ relative enforcement outcomes. By analyzing available CBP data, we found pockets of enforcement activity in some areas. For example, a majority of CBP’s seizure actions took place in a limited number of locations, with nearly three-fourths of aggregate seizure value accounted for by only 10 of more than 300 ports. These are a mix of

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55We reviewed agency statistics by field office and aggregated by fiscal year. Field office level statistics are considered law enforcement sensitive so details on the locations are not provided in this report.

56GAO-07-735.
ports, including a few of the nation’s largest and some that are smaller. In this report, we made recommendations to CBP to improve upon and better understand its IP enforcement activity through better analysis.\(^{57}\) We performed a similar analysis for DOJ using data on the number of defendants charged and number of cases filed by U.S. Attorney’s Offices and also found concentrations of activity for prosecution activity. For example, about 50 percent of IP-related cases were filed by around 10 percent of U.S. Attorney’s Offices during fiscal years 2001 through 2006. The same results were true for the number of defendants charged with IP crimes.

We also compared the U.S. Attorney’s Offices with the highest IP enforcement activity with the locations where CHIP units were created as of fiscal year 2006. Of the top 10 offices, ranked by number of IP cases filed in 2006, 7 had CHIP units, and the 2 most active offices had the largest CHIP units, measured by the number of attorneys working in the unit. This analysis suggests that the number of resources in a particular field office contributes to higher levels of activity; however, according to DOJ, other factors, such as crime level, can also affect activity levels. Our analyses illustrate the types of analysis that agencies can perform using their data, and insights they can obtain, to better inform management and resource allocation decisions. DOJ said that it performed similar analysis before deciding where to place CHIP units, but did not provide evidence that it conducts such analysis on a routine basis.

While all the agencies collected statistics to report broadly on their IP-related enforcement activities, most of the agencies have not clearly identified which IP enforcement actions relate to public health and safety and do not have data to track their efforts in this area, despite making this a priority enforcement area. By virtue of its mission, FDA’s data on IP-related enforcement specifically reflects its efforts to address IP violations that affect public health and safety. CBP has recently begun to monitor IP seizures related to public health and safety. In January 2008, it released seizure data for fiscal year 2007 that for the first time identified seizures in product categories that may involve public health and safety, e.g., pharmaceutical, electrical articles, and sunglasses. CBP officials told us that defining public health and safety seizures is difficult because not all

\(^{57}\)We recommended that CBP use existing data to understand and improve IP enforcement activity by analyzing IP enforcement outcomes across ports and other useful categories, such as modes of transport. See GAO-07-735.
seizures in a given category pose public health and safety risks, and such risks can be found across a broad range of products.

The other agencies lack data for identifying IP enforcement actions related to public health and safety. For example, ICE records IP enforcement under a general data field that applies to all types of IP cases. FBI and DOJ have some sub-categories for the types of IP investigations and prosecutions they pursue, but none is specific to public health and safety. Without specific data and definitions for IP-related enforcement efforts that impact public health and safety, agencies are unable to effectively track outcomes, inform management and resource allocation decisions, and report to Congress on an area of significant public importance.

Agencies have also taken few steps to clearly identify performance measures specifically for their efforts related to IP-related enforcement activities or establish performance targets to track their progress towards these efforts. We reviewed agencies' strategic plans and, while none had specific goals on IP enforcement, the CBP and DOJ plans listed IP enforcement as one issue to be addressed as part of working toward broader enforcement goals. We also examined agencies' public and internal planning documents or memos for IP enforcement and found that some had goals and objectives, but contained few performance measures or targets. Moreover, most of these are internal agency documents that are not available to the public. Neither ICE nor FDA have any additional planning documents for IP enforcement.

58 We reviewed the most recent agency strategic plans available, including DHS's 2004 strategic plan; CBP's strategic plan for fiscal years 2005-2010; ICE's interim strategic plan dated July 2005; DOJ's strategic plan for fiscal years 2007-2012; and FDA's strategic plan, dated August 2003.

59 CBP has an IP Rights Trade Strategy that contains certain performance measures and targets for IP enforcement, such as improving by 15 percent the efficiency of its efforts to target shipments containing IP violations and increasing the number and value of seizures meeting the strategy's goal by 15 percent. However, the document lacks baselines against which to measure progress. FBI articulates annual IP enforcement goals in a memo to its field offices, but does not include performance measures or targets. DOJ task force reports on IP enforcement contain recommendations for DOJ action, but no measures or targets. In 2007, DOJ developed its first IP enforcement strategy with enforcement objectives and some performance measures, but this document is for internal government use only, and we cannot disclose its contents.

60 For example, we found in our April 2007 report that CBP's IP Rights Trade Strategy is an internal document with limited distribution throughout CBP and therefore has limited usefulness as a tool to guide the agency's IP enforcement efforts. See GAO-07-735. DOJ's 2007 strategy is also for internal use only.
We asked agencies how they monitor their performance of IP enforcement activities. Most said they regarded their increasing trends in aggregate IP statistics (or outputs) as indicative of their progress. However, without performance measures related to these statistics, it is not clear how these statistics should be assessed because it is not clear what the agencies sought to achieve. We recognize that establishing measures and setting specific targets in the law enforcement area can be challenging. It is important that agencies carry out law enforcement actions that are based on merit and avoid the appearance that they strive to achieve certain numerical quotas, regardless of case quality. By definition, performance measures are a particular value or characteristic used to quantify a program’s outputs – which describe the products and services delivered over a period of time – or outcomes – which describe the intended result of carrying out the program. A performance target is a quantifiable characteristic that establishes a goal for each measure; agencies can determine the program’s progress, in part, by comparing the program’s measures against targets.

The Government Performance and Results Act of 1993\textsuperscript{61} incorporated performance measures as one of its most important features, and the establishment and review of performance measures are a key element of the standards for internal control within the federal government.\textsuperscript{62} We believe that measures and targets remain important components of measuring agency performance and enhancing accountability, particularly setting outcome-based measures that provide insight into the effectiveness of agencies’ efforts, not just levels of activity.\textsuperscript{63} More refined performance measurements that include outcome measures would allow agencies to better track their IP enforcement performance against their goals and give managers crucial information on which to base their organizational and management decisions. Performance assessment is also important in reporting progress to others, such as the IP Coordinator and NIPLECC.

\textsuperscript{61}The Government Performance and Results Act of 1993 (GPRA, Pub. L. No. 103-62) requires federal agencies to develop strategic plans with long-term, outcome-oriented goals and objectives, annual goals linked to achieving the long-term goals, and annual reports on the results achieved.


Doing so could help NIPLECC address its strategic planning weaknesses that we previously identified in our November 2006 report.\(^4\)

The National Intellectual Property Rights Coordination Center, an interagency mechanism created by the executive branch to improve federal IP enforcement and coordinate investigative efforts between ICE and FBI, has not achieved its mission or maintained the staffing levels set for it upon its creation. The center—intended to collect, analyze, and disseminate IP-related complaints from the private sector to ICE and FBI field offices for investigation—has suffered from a slow start, a lack of common understanding about its purpose and agencies’ roles, and limited private sector complaint information. As a result, the center has gradually shifted its focus toward educating the private sector about federal IP enforcement efforts. Congressional appropriators expressed support for the center’s original concept through various conference reports, which, over time, directed participating agencies to allocate appropriated funds to staff and operate the center. However, staffing levels have declined and the FBI no longer participates in the center. Plans are underway to move the center to a new location in early 2008, and according to officials from the other four key agencies, they have met with ICE to discuss what role their agencies might play in the center in the future.

The National Intellectual Property Rights Coordination Center is one of several interagency mechanisms for coordinating federal IP enforcement efforts. Unlike NIPLECC, which was established in law by Congress in 1999, the idea for creating the center arose from the work of the National Security Council’s Special Coordination Group on Intellectual Property Rights and Trade Related Crime, co-chaired by the FBI and legacy Customs. This group was formed in order to implement Presidential Decision Directive 42, issued in 1995, concerning international crime. In 1999, a consensus of the group members resulted in a multi-agency plan to improve the U.S. government’s efforts in IP enforcement, and the center

\(^4\)We reported that NIPLECC’s strategy was limited because it did not fully address the characteristics of an effective national strategy, missing elements such as a discussion of performance measures, resources, risk management, and designation of oversight responsibility. Although the strategy cites some output-related performance measures provided by the different agencies, we reported that these figures were presented without historical data on prior years or goals, limiting their usefulness to guide policy and decision makers in assessing performance, allocating resources, and balancing priorities. See GAO-07-74.
was created. According to ICE officials at the center, the center was directed by legacy Customs and included staff from Customs and FBI. After the formation of DHS, ICE took over legacy Customs’ role in directing the center and providing most of the DHS staff that were assigned to the center.

While the center and NIPLECC were both created to improve coordination among law enforcement agencies, the concept for the center gave it a greater operational focus than NIPLECC. The executive branch intended that the center would act as a hub for the collection, analytical support, and dissemination to investigative agencies of IP-related complaints from the private sector, including copyright infringement, trademark infringement, and theft of trade secrets. It envisioned that the center would coordinate and direct the flow of criminal referral reports on IP violations to the participating agencies’ investigative resources in headquarters and the field. In carrying out these roles, the center was expected to help integrate domestic and international law enforcement intelligence, consult regularly with the private sector, and generally act as a resource for IP complaints.

Congressional support for the center’s creation and role was noted through directives in various conference reports related to appropriations laws in fiscal years 2001 through 2004. These reports indicate that Congress also expected the center to be a dedicated effort to improve intelligence and analysis related to IP rights violations and gather IP enforcement information from other federal and state law enforcement agencies to augment investigations.\(^{65}\)

Like NIPLECC, the center has had difficulty defining its purpose and carrying out its law enforcement coordination mission.\(^{66}\) According to ICE,

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\(^{66}\) In 2004, we reported that after its creation, NIPLECC struggled to define its purpose, had leadership problems, and was regarded by Congress and the private sector as having had little discernable impact, having done little else in its early years than issue annual reports on federal IP enforcement efforts. This was due in part to a lack of clear expectations in its authorizing legislation. See GAO-04-912. Congress clarified NIPLECC’s mission in the 2005 Consolidated Appropriations Act, calling on it to (1) establish policies, objectives, and priorities concerning international IP protection and enforcement; (2) promulgate a strategy for protection of American IP overseas; and (3) coordinate and oversee implementation of the policies, objectives, priorities, and overall strategy for protection of IP overseas by agencies with IP responsibilities. See GAO-07-74.
FBI, and DOJ officials and our analysis, the center has not achieved its original mission for several reasons:

- The center got off to a slow start with limited operations in fiscal year 2000, and it took several years for it to become fully operational. For example, in 2004, we reported that many center staff were reassigned after the events of September 11, 2001, according to an FBI official. In addition, a change in leadership after the formation of DHS and the relocation of the center to new physical space in 2006 further impacted the continuity of the center’s operations.

- The flow of complaint information from the private sector to the center never materialized sufficiently to make the concept work, according to ICE and FBI officials. We reported in 2004 that the center was not widely used by industry, and this situation has persisted. For example, few of the private sector representatives that we contacted described working through the center to address their IP complaints.

- Participating agencies never reached agreement on how the center would operate and what their respective roles would be. FBI provided us a copy of a draft memorandum of understanding that it said it presented to ICE in fiscal years 2003, 2004, and 2005, to clarify operating procedures and agency roles. FBI also provided a copy of a 2004 letter from ICE acknowledging receipt of the draft memorandum and associated documents and indicating its intent to meet with FBI to discuss the matter. However, FBI officials said that neither ICE nor DHS followed up with FBI on this issue. ICE officials acknowledged having seen the memorandum of understanding in draft form but had no record or recollection of any discussions being held with FBI to discuss the memorandum.

Over time and in the absence of complaint information, the center began focusing on educating the private sector about federal IP enforcement agencies, approaches, and contacts, according to ICE officials at the center. Center staff participate in conferences, training programs, and trade shows around the country in which they disseminate information

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67GAO-04-912.
68In 2006, the center was moved from its original physical location to a temporary location that lacked the required security precautions to install FBI’s classified computer system. As a result, FBI removed its staff and computers from the center because it could no longer assure the security of its data.
69GAO-04-912.
about federal IP enforcement to the private sector. For example, center staff participated in 60 outreach and training events in fiscal year 2006 and 95 in fiscal year 2007. In addition, in 2007, ICE officials said the center began scheduling training sessions in selected cities around the country in which they bring together appropriate federal, state, and local law enforcement agencies and private sector representatives. The purpose of the training is to explain the region’s IP enforcement structure and strengthen involvement of the participants.

Through various conference reports, congressional appropriators supported the creation and staffing of the center by FBI, legacy Customs, and ICE, but agencies’ staffing levels at the center have declined. According to ICE officials, the center’s original concept envisioned 24 staff—16 from Customs and 8 from FBI. They said staff were to include a Director, investigative agents, intelligence analysts, and administrative support. The types of staff envisioned for the center further distinguish it as an operational entity compared to NIPLECC, which is not designed to carry out law enforcement. After the formation of DHS, the 16 Customs positions were transferred to DHS and taken over by as many as 16 ICE staff and 2 CBP staff. However, according to ICE and FBI officials, each agency’s staffing allotment has only periodically met the envisioned levels, and total staff currently at the center are about one-third of the level originally envisioned.

Conference reports for fiscal years 2001 through 2004 appropriations bills, at various times, indicated a desire for FBI, legacy Customs, and ICE to allocate funding for staffing and/or operations of the center. For example, in fiscal year 2001, the conference report directed FBI to allocate $612,000 to provide eight positions to the center. In fiscal years 2002, the conference report directed legacy Customs to allocate $5 million to support the hiring of agents dedicated to IP enforcement and to support and enhance the operation of the center. In fiscal year 2003, the conference report directed legacy Customs to allocate $5 million to continue center operations and $1.4 million to expand the center and its staffing. Congressional conferees encouraged Customs to use a portion of

Despite Congressional Expectations, the Center’s Staffing Levels Have Declined

70NIPLECC’s staff include the IP Coordinator, a policy analyst, press and legislative assistants, and various trade- or policy-oriented detailees from the participating agencies.

71Specifically, the conference report directed FBI to allocate “$612,000 (8 positions and 4 workyears, including 2 agents).” Conference Report 106-1005, accompanying P.L. 106-553.

the funds to establish the clearinghouse for referrals.\textsuperscript{73} In fiscal year 2004, the conference report directed ICE to allocate $6.4 million to the center.\textsuperscript{74}

We asked agencies how they responded to the conference report directives, with agencies responding as follows:

- FBI officials told us that the funding enabled them to authorize and begin filling positions noted in the congressional conference reports. FBI filled or nearly filled all eight positions during fiscal years 2001 through 2005. In fiscal year 2006, FBI continued to fill six of the positions, but removed its computers from the center due to security concerns and gradually had its staff spend less time working out of the center.\textsuperscript{75} Since fiscal year 2007, due to resource constraints, none of the FBI positions has been filled, and the FBI no longer participates in the center.

- CBP officials said that their records showed that in fiscal year 2002 legacy Customs placed seven staff (including two agents and four intelligence research specialists) in the center and assigned additional agents and intelligence research specialists to certain field offices and overseas locations to carry out IP enforcement. In fiscal year 2003, Customs officials told us they placed more agents and intelligence analysts in certain field locations and headquarters, but could not provide us with specific numbers. According to the Director of the center, following the formation of DHS, the two CBP positions were filled in 2004 but have been vacant for several years.

- ICE provided data indicating that, since fiscal year 2004, it spent about $3 million on investigative activities, set aside about $1.9 million for future construction costs for the center, spent about $1.2 million on direct salary

\textsuperscript{73}Conference Report 108-10 accompanying P.L. 108-7. The purpose of the clearinghouse was to gather IP rights information from other federal as well as state and local agencies. According to CBP officials, the funding that Customs was directed to provide in fiscal year 2003 was recurred at about $4.6 million to reflect the absence in that fiscal year of one-time costs that were present in fiscal year 2002. Also, CBP officials said that the direction to Customs to allocate an additional $1.4 million was reduced to about $1.39 million following a $9,100 rescission.

\textsuperscript{74}Conference Report 108-280 accompanying P.L. 108-90. According to ICE officials, the funding that it was directed to provide in fiscal year 2004 was reduced to about $6.36 million due to a rescission contained in the Consolidated Appropriations Act, 2004 (P.L. 108-199).

\textsuperscript{75}See footnote 66.
costs, and spent the remainder on operating costs for the center. ICE staffing levels at the center have declined from 15 in 2004 to 8 in 2007.

**ICE Views Center’s Relocation as an Opportunity to Revisit Center’s Purpose and Agency Roles**

In early 2008, ICE plans to move the center to a new location that is being configured specifically for the center and some additional functions. According to ICE officials, the new center will continue to focus on private sector outreach. The role that the center will play in coordinating referrals and investigations among the IP enforcement agencies, however, remains unclear. ICE officials said they view the relocation as an opportunity to return the center to its original concept and purpose. NIPLECC’s IP Coordinator said that as an entity staffed by, and located in, a law enforcement agency, the center can play a role in facilitating law enforcement coordination at an operational level that NIPLECC cannot. However, the IP Coordinator agreed that there are mixed views among IP enforcement agencies about the usefulness of the center.

In preparation for the move, ICE officials said they had met with FBI, DOJ, CBP, and FDA to offer them space in the center and ask them to permanently assign staff there; however, agencies’ reactions are mixed. FDA plans to staff one special agent at the center initially and will send additional agents later if its workload at the center justifies additional staff. FDA officials said that the agency decided to staff an agent at the center despite its limited resources because counterfeit drugs pose a significant threat to the public health and are a high priority to FDA. According to an official in FDA’s Office of Criminal Investigations, a significant portion of FDA’s counterfeit drug investigations are conducted jointly with ICE, and the center may facilitate a coordinated law enforcement approach.

According to DOJ and FBI officials, staff will not be placed at the center unless there is a more operational focus in addition to the training and outreach currently provided. More specifically, DOJ and FBI would like there to be some initial analysis and investigation after an industry referral is received at the center before information is passed on to field investigative agents. Further, even if FBI sees the center taking a more operational focus, the agency would have to request additional staff.

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76 The center will be co-located with two other ICE initiatives: ICE Mutual Agreement between Government and Employers (IMAGE) and the Washington Field Office’s Document and Benefit Fraud Task Force.
resources to be able to assign personnel, since currently none is available. CBP officials said they do not plan to allocate any staff to the center.

According to ICE and FDA officials, no discussions have taken place to outline the purpose of the new center or define how agencies would coordinate their enforcement activities at the center.

**Conclusions**

Federal IP enforcement agencies confront growing challenges in protecting the United States against counterfeit and pirated goods. IP crimes appear to be on the rise, and the key law enforcement agencies and FDA need to work efficiently and effectively to contend with this trend. Most federal IP enforcement activity has increased in recent years. However, because IP enforcement is generally not a top agency priority, few resources are dedicated solely to this task, and agencies may spend fewer resources on IP enforcement than on higher priority issues. Despite the general increases in IP enforcement activity, agencies have taken little initiative to improve their data or evaluate their enforcement activity in ways that would enable them to identify and track certain trends or enforcement outcomes, like regional variations in enforcement activity and types of IP-infringing goods commonly enforced. Performing this type of analysis could help the agencies make further improvements in their IP enforcement activity by making more effective management decisions and resource allocations. At the same time, setting performance measures and targets for IP enforcement activities could help the agencies better assess their progress toward their goals. Finally, collecting better data, analyzing them, and reporting on progress toward goals could help make the key IP enforcement agencies more accountable to the public and Congress, particularly regarding their efforts to address IP-infringement that affects public health and safety. The need for such improvements among IP enforcement agencies mirrors weaknesses we found previously with NIPLECC, in which the lack of clarity over performance measures, resource requirements, and oversight responsibilities limited NIPLECC’s ability to prioritize, guide, implement, and monitor the combined efforts of multiple agencies to protect and enforce IP rights.

One area where IP enforcement has not increased is CBP’s enforcement of exclusion orders. U.S. companies spend millions of dollars to argue their allegations of IP infringement before the U.S. International Trade Commission, but the Commission relies on CBP to enforce its decisions. CBP has allocated few resources to carry out its role in this complex area, lacks data to track its enforcement of exclusion orders, and has not given sufficient attention to addressing the procedural weaknesses that we
identify. Given the potential for these orders to affect large volumes of trade, CBP has a responsibility to improve its enforcement of exclusion orders.

As agencies consider ways to further improve federal IP enforcement, the relocation of the National Intellectual Property Rights Coordination Center presents an opportunity for NIPLECC and the key IP enforcement agencies to reassess the need for law enforcement coordination in this area and the best way to achieve it. As part of this discussion, NIPLECC and the agencies need to examine the center’s mission, what outcomes they expect from the center, and what role key agencies should play, if any, in the center’s future. Given Congress’ sustained interest in improving federal IP enforcement and its past support for the center, providing this information to Congress could help better inform Congress about what contributions to IP enforcement it should expect from the center.

Recommendations for Executive Action

To better inform management and resource allocation decisions and report on agency achievements, we recommend that the Attorney General and the Secretaries of Homeland Security and Health and Human Services direct their agencies to take the following four actions:

For ICE, FBI, FDA, and DOJ:

- systematically analyze enforcement statistics to better understand variations in IP-related enforcement activity.

For CBP:

- continue to take steps to better identify IP seizures that pose a risk to the public health and safety of the American people, and collect and report this data throughout the agency and to Congress.

For ICE, FBI, and DOJ:

- take steps to better identify enforcement actions against IP-infringing goods that pose a risk to the public health and safety of the American people, and collect and report this data throughout each agency and to Congress.

For CBP, ICE, FBI, and DOJ:
establish performance measures and targets for IP-related enforcement activity and report such measures, targets, and actual performance to NIPLECC and Congress.

To better inform Congress and affected rights holders regarding its enforcement of exclusion orders and address certain procedural weaknesses, we recommend that the Secretary of Homeland Security direct the Commissioner of CBP to take the following three actions:

- identify factors currently limiting their enforcement capabilities and develop a strategy for addressing those limitations along with a timeline for implementing the strategy;
- begin collecting data on the number of exclusions, in total and per exclusion order; and
- examine CBP’s ability to develop regulations to allow notification of exclusions to affected rights holders, and if authorized, develop such regulations.

To clarify the mission and structure of the National Intellectual Property Rights Coordination Center, we recommend that the Attorney General and the Secretary of Homeland Security, in consultation with NIPLECC, direct their IP enforcement agencies to take the following three actions:

- reassess the National Intellectual Property Rights Coordination Center’s mission and how its future performance will be assessed;
- define agencies’ role in the center and the number and types of resources needed to operate the center; and
- report to Congress on the center’s redefined purpose, operations, required resources, and progress within 1 year of the center’s relocation.

Agency Comments and Our Evaluation

We provided a draft of this report to DHS, DOJ, and HHS for their review and comment. CBP and ICE provided comments through DHS. DHS, CBP, and ICE concurred with our recommendations. DOJ did not indicate whether it agreed or disagreed with our recommendations. HHS commented that it disagreed with our recommendation that FDA develop performance measures and targets for IP enforcement. In light of the agency’s public health and safety mission, we determined that it was inappropriate to require FDA to develop law enforcement-related
measures and targets, and no longer recommend this. However, given the importance of understanding the nature of IP violations that affect public health and safety, we now recommend instead that FDA more systematically analyze its IP enforcement statistics (see p. 43). We believe this is a more appropriate recommendation because FDA said that it already monitors its IP enforcement criminal investigations to discern trends. In response to other comments the agencies made, we also modified two recommendations to give the agencies more flexibility in identifying which of their IP enforcement actions relate to public health and safety. Instead of recommending that the agencies create categories and definitions of such actions, as we did in the draft report, we recommend that they take steps to better identify these actions (see p. 43). A summary of each agency’s comments and our evaluation follows.

CBP commented that the report inaccurately states that it lacks data and definitions for IP-related enforcement efforts that impact public health and safety, saying it reported this data in its fiscal year 2007 seizure statistics. In response, we modified the final report to note that CBP began reporting on IP seizures related to public health and safety for the first time in January 2008 (see p. 33). CBP also commented that the report’s finding that it lacks performance measures for IP enforcement is not completely accurate and cited its “National IPR Trade Strategy.” We added information to the final report about this document (see p. 34), but continue to believe that CBP needs to incorporate IP enforcement measures and targets into its agency-wide strategic plan, which it has said it intends to do. Finally, CBP repeated comments made about our April 2007 report regarding an analysis that we proposed it could undertake to better understand its enforcement outcomes. We disagreed with CBP’s comments at that time and continue to believe that CBP, and the other agencies, can make better use of existing data to understand their IP enforcement efforts and outcomes. DHS’s written comments and our detailed response appear in appendix IV.

DOJ made several comments about ways in which it believes the report understates its IP enforcement achievements. For example, DOJ cited percent increases between select years for certain indicators to demonstrate its increased enforcement results. However, the report takes a more systematic approach to evaluating overall federal IP enforcement

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efforts by examining multiple indicators at multiple agencies over a 6-year period. We believe that the report’s approach and assessment is fair and valid. DOJ also commented we did not sufficiently acknowledge increases in training and resource allocations for IP enforcement, particularly as relates to its CHIP units. In fact, as was true for the draft report, the final report discusses growth in CHIP units and numbers of IP-trained attorneys (see p. 20). Finally, DOJ commented that the report inaccurately characterizes its efforts to analyze IP enforcement statistics by district. We modified the report to add information that DOJ analyzed IP enforcement statistics when deciding where to place CHIP units; however, DOJ never provided evidence that it conducts such analysis on a routine basis (see p. 33). We continue to believe that systematically conducting such analysis can help DOJ determine whether its allocation of resources is producing the kind of increases in IP enforcement outcomes that it desired.

DOJ commented that the report inaccurately describes its efforts to establish performance measures or goals to assess its IP enforcement achievements. In response, we added information to the discussion of performance measurement about certain DOJ documents that contain such goals and measures, and cited again the DOJ task force reports on IP enforcement, which had been mentioned earlier in the report (see p. 34). However, the task force reports contain only recommendations for DOJ action, not goals with associated performance measures. A few of these recommendations are structured like performance goals, such as “target large, complex organizations that commit IP crime” or “prosecute IP offenses that endanger the public’s health or safety,” but the task force report provides no indication of how DOJ will measure progress toward these recommendations. DOJ commented that developing numeric or percentage targets linked to its performance measures could create the potential for case quotas or thresholds. We agree that setting performance measures and targets in the law enforcement arena is difficult, and we added information to the report to further clarify the sensitivities associated with doing this (see p. 35). However, we continue to believe that it is important, and possible, for DOJ to develop performance measures and targets to help it, and others, determine whether its overall IP enforcement efforts are achieving performance goals and focused on the right issues, and whether its resource allocations devoted to this area are contributing to the desired results. DOJ’s written comments and our detailed response appear in appendix V.

HHS expressed concerns about setting performance measures and targets that were similar to those raised by DOJ. While we no longer direct this
recommendation to FDA, we continue to believe that is it important and possible for law enforcement agencies to set useful performance measures and targets to guide and assess their efforts. FDA’s written comments and our detailed response appear in appendix VI.

DHS, DOJ, and HHS also provided technical comments, which we incorporated as appropriate.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to appropriate congressional committees and the Secretaries of the Departments of Homeland Security and Health and Human Services; the Attorney General; the Chairman of the U.S. International Trade Commission; and NIPLECC’s IP Coordinator. We will also make copies available to others on request. In addition, the report will be available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-4347 or yagerl@gao.gov. Contact points for our Office of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix VII.

Sincerely yours,

Loren Yager, Director
International Affairs and Trade
Appendix I: Scope and Methodology

The Ranking Minority Member of the Senate Subcommittee on Oversight of Government Management, the Federal Workforce and the District of Columbia, Committee on Homeland Security and Governmental Affairs, asked us to (1) examine federal agencies’ roles, priorities, and resources devoted to intellectual property (IP) enforcement, (2) evaluate agencies’ IP-related enforcement statistics and achievements, and (3) examine the status of the National Intellectual Property Rights Coordination Center.

Based on our previous work and background research, we determined that the key federal law enforcement agencies carrying out IP enforcement are Customs and Border Protection (CBP), Immigration and Customs Enforcement (ICE), the Federal Bureau of Investigation (FBI), and the Department of Justice (DOJ). In addition, we included the Food and Drug Administration (FDA) due to its role in investigating counterfeit versions of products it regulates. To describe the federal structure that carries out IP enforcement, we met with CBP, ICE, DOJ, FBI, and FDA officials at the agencies headquarters, and, for all agencies except FDA, met with officials in multiple field locations. The locations we visited are not disclosed in this report for law enforcement reasons.\(^1\) We also met with the International IP Enforcement Coordinator (IP Coordinator). We reviewed agency documents to understand policies and practices related to IP enforcement and discussed the processes by which these agencies interact with each other in conducting IP enforcement. We also reviewed prior GAO reports that examined the federal IP enforcement structure, agencies’ role, and key coordinating mechanisms.\(^2\) To determine agencies’ IP enforcement priorities, we examined strategic and other planning documents, including agency memos detailing goals and objectives related to IP enforcement. In some instances, agency documents were law enforcement sensitive; therefore, the details have not been included in the report and only information that was discussed openly in interviews or in public documents and forums has been used.

To determine resources dedicated to IP enforcement, we spoke with agency officials, obtained data on the number of staff dedicated to IP enforcement, and analyzed data, where available, on staff time spent on IP enforcement. In particular, we obtained data on (1) the number of criminal

\(^1\)Our April 2007 report included analysis and information about IP enforcement at the ports we visited. We withheld information on these ports’ identity for law enforcement reasons. Therefore, we cannot disclose this information in this report.

\(^2\)GAO-04-912; GAO-07-74; and GAO-07-735.
investigative case hours that ICE and FDA field offices recorded under
codes used to track IP enforcement; and (2) the average number of agents
on board that were working IP criminal cases, as reported by FBI field
offices. We obtained data covering fiscal years 2001 through 2006, except
for FDA investigative case hours for counterfeit products, which the
agency has only been tracking since fiscal year 2003. We reviewed these
data for obvious errors and consistency with publicly reported data, where
possible. When we found discrepancies, we brought them to the attention
of relevant agency officials and worked with them to correct the
discrepancies before conducting our analyses. On the basis of these
efforts, we determined that these data were sufficiently reliable for our
purposes. To make similar comparisons across the agencies, we converted
ICE and FDA data on criminal case hours into full-time equivalents (FTE)
using information that the agencies provided and confirmed with FBI
officials that we could use FBI’s measurement as equivalent to the FTE
measurement for time spent by ICE and FDA IP investigations.

To examine agencies’ IP enforcement activity, we analyzed data from
fiscal year 2001 to fiscal year 2006 on CBP IP seizures, penalties, and
exclusion activities; the number of criminal cases opened in ICE, FBI, and
FDA’s Office of Criminal Investigation field offices that were recorded as
IP enforcement cases; ICE, FBI, and FDA arrests, indictments, and
convictions stemming from their IP investigations; and the numbers of
referrals of IP cases to DOJ from the investigative agencies, IP cases that
DOJ filed, defendants charged in those cases, defendants convicted of IP
crimes, defendants imprisoned, and sentences awarded. Information on
CBP seizures and penalties is drawn from our April 2007 report. In
addition, we obtained data from CBP on its Trade Alerts as of July 2007, as
well as the number of targeting instructions it had in place for each Trade
Alert in each of fiscal years 2003 through 2006 and the number of exams,
IP violations, and seizures it has recorded as a result of those instructions.
We discussed key law enforcement activities with ICE, FBI, FDA, and DOJ
and determined what data the agencies record and what activities they
report on internally. We then requested them to extract data from their
systems on these key activities when they were performed for IP
enforcement. For the most part, investigative agency data reflect activities
that are coded as IP enforcement, while DOJ data reflect activities in
which key IP enforcement statutes are cited. In general, the agencies said
that the data they provided reflected most, but perhaps not all, of their
activity related to IP enforcement.

In order to collect uniform data on IP enforcement activities, we worked
with each agency to develop the parameters by which we would request
Appendix I: Scope and Methodology

data from their systems. In addition, we worked with officials at each
agency to develop a thorough understanding of the data that we received.
We reviewed the data we obtained for obvious errors and consistency with
publicly reported data, where possible. When we found discrepancies, we
brought them to the attention of relevant agency officials and worked with
them to correct the discrepancies before conducting our analyses. For
example, we determined that CBP provided information on Trade Alerts
that related to Exclusion Orders that were no longer in effect. CBP agreed
and revised the number of Trade Alerts on its Web site. Also, the data we
report on ICE’s arrests, indictments, and convictions are different from
data it has reported publicly in the IP Coordinator’s quarterly IP
enforcement updates. ICE officials said that the system from which it
obtains this data is a “live system,” meaning that data pulled from the
system on different dates may not be the same. ICE officials cited updates
to case information as one reason that data might differ over time. In
addition, the parameters that ICE advised us to use when requesting ICE’s
data on IP enforcement cases differed somewhat from the parameters that
ICE used. Finally, we found some inconsistencies with FBI’s IP
enforcement data. We discussed these discrepancies with FBI and made
changes to the data accordingly. We asked FBI officials familiar with the
agency’s IP enforcement efforts to review the final data set for accuracy.
We did not find discrepancies with FDA or DOJ data and used the most
current data sets they provided for the 6 fiscal years we requested. Based
on our discussions of internal controls and ability to address data
discrepancies with the agencies, we determined that the data are
sufficiently reliable to report IP enforcement activity. To assess federal
agencies’ achievements in IP-related enforcement activity, we reviewed
agency priorities, goals, and objectives and compared them to the types of
data agencies collected. We also asked program officials how they used
their IP enforcement data to assess performance and inform management
and resource allocation decisions.

We also talked to private sector representatives to better understand how
counterfeit and piracy affects their businesses and obtain their views on
federal IP enforcement. We obtained different company contacts from

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3The IP Coordinator reports quarterly on IP enforcement. These reports are posted on the
Stop Fakes Web site (http://www.stopfakes.gov) and have been distributed at public events
such as the U.S. Chamber of Commerce’s Coalition Against Counterfeiting and Piracy
monthly meetings. Several of these reports, including the report for the third quarter of
2007, have contained data on ICE’s arrest, indictments, and convictions. However, the data
was not included in the fourth quarter report for 2007.
Appendix I: Scope and Methodology

conferences, federal agencies working with private sector, and our own research. We developed structured interview questions to understand industry views regarding federal IP enforcement efforts and private companies’ own efforts to protect their IP. We selected eight sectors based on our participation in trade conferences and discussions and information from organizations such as the U.S. Chamber of Commerce that have anti-counterfeiting campaigns and are affected by counterfeiting and piracy. We interviewed 22 companies and 8 industry associations across those sectors. The sectors we selected were: consumer electronics, entertainment and media, luxury goods and apparel, health and food, Internet, pharmaceutical, software, and manufacturing. For the most part, we interviewed at least one industry association and two companies in each sector. Most of the companies we spoke with were large companies because the prevalence of their brand in the market has made them targets for counterfeiting and piracy. We analyzed industry interviews using a systematic coding scheme to identify common themes and responses to our questions.

To examine the intended purpose and funding of the National Intellectual Property Rights Coordination Center, we met with ICE and FBI officials associated with the center to discuss its evolution, role, and staffing levels; reviewed agency documents that articulated the center’s purpose; and analyzed Congressional budget documents that reflected funding related to the center. Specifically, we reviewed appropriation legislation and related reports of the House and Senate Committees on Appropriations and relevant subcommittees for fiscal years 2001 through 2006 to determine what funds and additional instructions were provided to ICE, FBI, and legacy Customs related to staffing and operating the center. We then requested information from ICE, FBI, and CBP about what funds were received and how the funds were used. We also discussed the center’s future role with ICE, FBI, FDA, and DOJ officials, and the NIPLECC IP Coordinator.

We conducted this performance audit from December 2006 through March 2008 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.
The federal government plays a role in granting protection for and enforcing IP rights. It grants protection by approving patents or registering copyrights and trademarks. These IP rights grant registrants limited exclusive ownership over the reproduction or distribution of protected works (copyright), the economic rewards the market may provide for their creations and products (trademark), or the right to exclude others from using, making, and selling devices that embody a claimed invention (patent). The federal government enforces IP rights by taking actions against those accused of their theft or misuse. Enforcement actions include both civil and criminal penalties. U.S. laws criminalize certain types of IP violations, primarily copyright and trademark violations, and authorize incarceration or fines. These laws are directed primarily toward those who knowingly produce and distribute IP-infringing goods, rather than those who consume such goods. Although U.S. laws do not treat patent violations as a crime, the federal government does take actions to protect patents and authorizes civil enforcement actions against infringers.

Table 3 summarizes federal protection and enforcement of IP rights under U.S. law. ¹

¹In addition to the laws cited in the table, the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.) provides legal authority for FDA to conduct counterfeit product investigations and enforcement actions.
## Appendix II: Federal Protection and Enforcement of IP Rights under U.S. Law

Table 3: Summary of Federal Protection and Enforcement of IP Rights under U.S. Law

<table>
<thead>
<tr>
<th>Type of IP protection</th>
<th>Criminal penalties</th>
<th>Non-criminal actions and penalties (by federal government)</th>
<th>Civil remedies and penalties (available to rights holders and other victims)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>U.S. Copyright</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Criminal Infringement for Profit</td>
<td>Individuals</td>
<td>1st offense, maximum 5 years imprisonment and $250,000 fine or twice gain/loss; 2nd offense, maximum 10 years imprisonment</td>
<td>Civil forfeiture available (of infringing copies, and plates, mold, tapes, or other equipment from which infringing copies can be made)</td>
</tr>
<tr>
<td></td>
<td>Corporations</td>
<td>$500,000 or twice gain/loss</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Criminal forfeiture available</td>
<td></td>
</tr>
<tr>
<td>Bootleg Recordings of Live Musical Recordings (unauthorized fixation of and trafficking in sound recordings and music videos of live musical performances)</td>
<td>Individuals</td>
<td>1st offense, maximum 5 years imprisonment and $250,000 fine or twice gain/loss; 2nd offense, 10 years imprisonment</td>
<td>Civil forfeiture available (for bootlegs imported into the U.S.)</td>
</tr>
<tr>
<td></td>
<td>Corporations</td>
<td>$500,000 or twice gain/loss</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Criminal forfeiture available</td>
<td></td>
</tr>
<tr>
<td>Camcording (unauthorized recording of motion pictures in motion picture exhibition facility)</td>
<td>Individuals</td>
<td>1st offense, maximum 3 years imprisonment and $250,000 fine or twice gain/loss; 2nd offense, maximum 6 years imprisonment</td>
<td>No specific civil remedies for camcording, although camcording is actionable as copyright infringement.</td>
</tr>
<tr>
<td></td>
<td>Corporations</td>
<td>$500,000 fine or twice gain/loss</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Criminal forfeiture available</td>
<td></td>
</tr>
<tr>
<td>Large-Scale Infringement without Profit Motive (reproduction or distribution over any 180-day period/more than $1,000 total retail value)</td>
<td>Individuals</td>
<td>1st offense, maximum 3 years imprisonment and $250,000 fine or twice gain/loss; 2nd offense, 6 years imprisonment</td>
<td>Civil forfeiture available (even where it is neither willfully committed nor for profit) is actionable under 17 U.S.C. § 501 et seq.</td>
</tr>
<tr>
<td></td>
<td>Corporations</td>
<td>$500,000 fine or twice gain/loss</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Criminal forfeiture available</td>
<td></td>
</tr>
</tbody>
</table>

Copyright infringement (even where it is neither willfully committed nor for profit) is actionable under 17 U.S.C. § 501 et seq. For willful copyright infringement, copyright owners may obtain injunctions, ex parte orders to seize infringing items, and recover actual damages or statutory damages of up to $150,000 per work infringed, as well as attorneys' fees and costs.
## Appendix II: Federal Protection and Enforcement of IP Rights under U.S. Law

<table>
<thead>
<tr>
<th>Type of IP protection</th>
<th>Criminal penalties</th>
<th>Non-criminal actions and penalties (by federal government)</th>
<th>Civil remedies and penalties (available to rights holders and other victims)</th>
</tr>
</thead>
</table>
| Distribution of Pre-Release Works or Material over Publicly-Accessible Computer Network for Commercial Purposes (17 USC 506(a)(1)(C) and 18 USC 2319(d)) | **Individuals**  
1st offense, maximum 5 years imprisonment and $250,000 fine or twice gain/loss; subsequent offense, 10 years imprisonment  
**Corporations**  
$500,000 fine or twice gain/loss  
Criminal forfeiture available | Civil forfeiture available | Actionable as copyright infringement (see above). |
| Distribution of Pre-Release Works or Material over Publicly-Accessible Computer Network Not for Commercial Purposes (17 USC 506(a)(1)(C) and 18 USC 2319(d)) | **Individuals**  
1st offense, maximum 3 years imprisonment and $250,000 fine or twice gain/loss; subsequent offense, 6 years imprisonment  
**Corporations**  
$500,000 fine or twice gain/loss  
Criminal forfeiture available | Civil forfeiture available | Actionable as copyright infringement (see above). |
| Use of Technology to Violate Anti-Circumvention Systems and Anti-Piracy Protections and Protection of Integrity of Copyright Management Information (17 USC 1201-1204) | **Individuals**  
1st offense, maximum 5 years imprisonment and $500,000 fine or twice gain/loss; 2nd offense, maximum 10 years imprisonment and $1 million fine or twice gain/loss | Civil court action available, including  
--temporary or permanent injunction  
--impoundment  
--actual and statutory damages  
--costs  
--attorney's fees  
--remedial modification or destruction of violating product  
--triple damages for repeat violations within 3 years of initial violation | |
| Trafficking in counterfeit labels, illicit labels, or counterfeit documentation or packaging (18 USC 2318) | **Individuals**  
Maximum 5 years imprisonment and $250,000 fine or twice gain/loss  
**Corporations**  
$500,000 fine or twice gain/loss  
Criminal forfeiture available | Civil forfeiture available | Available civil remedies include  
--temporary or permanent injunction  
--impoundment  
--attorney's fees and costs  
--actual damages and any additional profits  
--statutory damages of up to $25,000 per violation |
## Appendix II: Federal Protection and Enforcement of IP Rights under U.S. Law

<table>
<thead>
<tr>
<th>Type of IP protection</th>
<th>Criminal penalties</th>
<th>Non-criminal actions and penalties (by federal government)</th>
<th>Civil remedies and penalties (available to rights holders and other victims)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>U.S. Trademark</strong></td>
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</tr>
<tr>
<td>Trafficking in Counterfeit Goods or Services (using counterfeit mark) (18 U.S.C. § 2320)</td>
<td><strong>Individuals</strong></td>
<td>1st offense, maximum 10 years imprisonment and maximum $2,000,000 fine or twice gain/loss; 2nd offense, maximum 20 years imprisonment and maximum $5,000,000 fine or twice the gain/loss</td>
<td>Civil forfeiture available.</td>
</tr>
<tr>
<td></td>
<td><strong>Corporations</strong></td>
<td>1st offense, maximum $5,000,000 fine or twice gain/loss; subsequent offense, maximum $15,000,000 fine or twice the gain/loss</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>Criminal forfeiture available.</td>
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<tr>
<td><strong>U.S. Patent</strong></td>
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</tr>
<tr>
<td>False Patent Marking (35 U.S.C. § 292)</td>
<td><strong>Individuals</strong></td>
<td>No criminal penalties, but criminal fines based on criminal conduct related to patents.</td>
<td>Maximum $500 fine for every offense</td>
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<tr>
<td><strong>U.S. Trade Secrets</strong></td>
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<tr>
<td>Economic Espionage (18 U.S.C. § 1831)</td>
<td><strong>Individuals</strong></td>
<td>maximum 15 years imprisonment or $500,000 fine or twice gain/loss, or both</td>
<td>The Attorney General may obtain injunctions against violations.</td>
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</tr>
<tr>
<td></td>
<td><strong>Corporations</strong></td>
<td>$10,000,000 fine or twice gain/loss</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>Criminal forfeiture available</td>
<td></td>
</tr>
<tr>
<td>Theft of Trade Secrets (18 US 1832)</td>
<td><strong>Individuals</strong></td>
<td>1st offense, maximum 10 years imprisonment or $250,000 or twice gain/loss; 2nd offense, 10 years imprisonment</td>
<td>The Attorney General may obtain injunctions against violations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Corporations</strong></td>
<td>Maximum $5,000,000 fine or twice gain/loss</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>Criminal forfeiture available</td>
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</tr>
</tbody>
</table>

Source: GAO analysis of DOJ documents and review by DOJ’s Criminal Division.
Appendix III: Private Sector Views on Federal IP Enforcement Efforts

A number of companies have been affected by counterfeiting and piracy, particularly as criminal activity has increased in recent years. As part of our review of federal IP enforcement efforts, we identified companies and industry associations that are actively involved in anti-counterfeiting and piracy activities. We interviewed 8 industry associations and 22 companies across 8 sectors, including consumer electronics, luxury goods and apparel, pharmaceuticals, and software. The views obtained through these interviews cannot be generalized across sector or industry overall given that our sample size was small. Industry responses produced a mix of views on federal efforts to enforce intellectual property rights, with some companies reporting positively about specific agency actions and others that were more critical of federal actions. A selection of industry views by sector are presented below based on analysis and synthesis of interview responses around common themes. For the most part, each bullet represents a different company or association representative. These views are not direct quotes and have been edited as needed for clarity and readability.

Various Companies Are Impacted by Counterfeiting and Piracy

Table 4 highlights industry views on the impact of counterfeiting and piracy.

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1Most of the companies we interviewed were large companies with anti-counterfeiting and/or piracy initiatives.
Appendix III: Private Sector Views on Federal IP Enforcement Efforts

Table 4: Summary of Industry Representatives’ Views on the Impact of Counterfeiting and Piracy, by Sector

<table>
<thead>
<tr>
<th>Sector</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumer electronics</td>
<td>• Federal law enforcement efforts have improved very impressively over the past three years. There is better coordination and more resources, but the problem is growing and now there is an economic and health and safety issue...The magnitude of the federal law enforcement effort is still not commensurate with magnitude of [counterfeit and pirated] products.</td>
</tr>
</tbody>
</table>
| Luxury goods/apparel    | • Beyond a loss to businesses, there is a huge loss to the Treasury and the national infrastructure that results from the sale of counterfeit goods.  
• Most counterfeit goods are sold by small businesses that intentionally mix real products with counterfeit products so people can’t tell. |
| Health/food             | • The main issue with regard to counterfeiting and piracy is fast moving consumer goods. It has become an increased problem as personal care products that have safety issues are found in large retail stores and grocery stores. |
| Internet                | • Losses to property rights owners from counterfeiting and piracy can occur through Internet/online auctions.                                                                                     |
| Pharmaceutical          | • Counterfeit medicines place public health and safety at risk, have the potential to damage patient confidence in the branded medicine, and negatively impact sales of the authentic medicines. |
| Software                | • The impact of software piracy and counterfeit software varies by company and losses are difficult to calculate. Most pirated software is in the form of Internet downloads or mail order piracy that reduces company profits and taxes paid to the government, while counterfeit software poses greater risks to consumers in terms of potential damage to their computers. |
| Manufacturing           | • It is difficult to calculate direct losses for some companies, but estimated losses in this sector have been reported as high as $1 billion.                                                                 |

Source: GAO analysis of private sector responses.

Industry Concerned over Lack of Resources to Carry Out IP Enforcement

Some industry representatives expressed concern about the federal government’s ability to carry out IP enforcement due, in part, to a lack of dedicated resources. While several companies said that federal IP enforcement efforts have increased, 14, or nearly half, of the representatives we contacted said there is a shortage of resources to carry out IP enforcement. For example, one company we interviewed said that CBP has made improvements over the last couple of years, but the scope of its efforts is still not up to the problem, and that more resources are needed to perform risk analysis and modeling to determine the origin of counterfeit goods. Another company representative said that the task is large compared to the federal resources applied, especially because the number of counterfeiters is increasing but federal resources have remained constant. Companies reported increasing their own resources to focus on IP enforcement, with 15 stating that they employ or contract private investigators and/or have in-house resources dedicated to IP investigations and anti-counterfeiting activity. Table 5 highlights specific
representatives’ statements about the level of federal resources dedicated to IP enforcement.

Table 5: Summary of Industry Representatives’ Views on Federal Resources Dedicated to IP Enforcement, by Sector

<table>
<thead>
<tr>
<th>Sector</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Consumer electronics  | • CBP has greatly improved over the past couple of years, but the scope of the effort is still not up to the problem – they need more staff resources that do risk analysis and modeling to determine where counterfeit goods may be coming from and to help them target inspections more.  
  • There is some need in some places around the country for specific CBP resources dedicated to the IP issue. It doesn’t have to be the case at every port. With more dedicated resources to IP, we would see seizure numbers go up even more.  
  • Federal IP law enforcement agencies are challenged because of their limited staff resources. |
| Luxury goods/apparel  | • There is a lack of resources and money available to CBP, and it would have to increase in both those areas to improve on the number of seizures.                                                                |
| Health/food           | • CBP is able to screen only a certain percentage of goods that come in, so additional resources would be helpful.                                                                                           |
| Pharmaceutical        | • There is a need for increased and dedicated human and financial resources in the federal government.  
  • Federal agencies have to prioritize, but at the same time everyone knows that the number of counterfeiters is increasing while available federal resources are constant. |
| Software              | • Federal IP enforcement efforts are hampered by the limited resources, such as staff, technology, and funding devoted to IP enforcement. CBP staff at ports face incredible challenges in carrying out their jobs given the quantity of U.S. trade. Federal law enforcement staff are overworked, need more high-tech equipment and technology, and should have additional training. |

Source: GAO analysis of private sector responses.

Industry Cites Lack of Information Sharing and Unclear Agency Roles as Barrier to Effective Enforcement and Coordination

Representatives from 12 out of 30 companies and associations we interviewed told us that better information sharing is needed between the public and private sector; for example, one company representative said that agencies should let companies know whether the information they pass on to law enforcement is useful. In the case of CBP seizures, some representatives remarked on the need to obtain more detailed information about imports suspected of infringing on their products, such as the origin of the shipments. One company representative commented that it used to get information on suspect products from CBP officers, but it has not received this type of information from CBP recently. One company representative said that the company has referred information to the National Intellectual Property Rights Coordination Center, but has rarely received feedback on whether the information it provided was useful. Another company said that it has to continuously follow up to get updates.
Several companies and associations we interviewed remarked that the federal IP enforcement structure is not very clear, and companies, particular smaller ones, have a hard time knowing who to contact for IP issues. For example, one association said that there is no formal process for referring cases to law enforcement and that information on the structure needs to be clearer and more efficient. While larger companies may be more familiar with [law enforcement] agencies’ procedures and contacts, smaller companies don’t know where to begin. Another association said that agency responsibilities are unclear and may overlap. Table 6 highlights industry representatives’ general comments on their coordination with federal IP enforcement agencies.

Table 6: Summary of Industry Representatives’ Views on Coordination with Federal IP Enforcement Agencies, by Sector

<table>
<thead>
<tr>
<th>Sector</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Consumer electronics    | • It would be helpful if there was more information about the right levels of government to contact regarding law enforcement issues. The Chamber of Commerce’s Coalition against Counterfeiting and Piracy provides a lot of support in this area.  
|                         | • When leads are referred to the National Intellectual Property Rights Coordination Center, we don’t hear back from them and have not received feedback on whether the information we provided is helpful in leading to an enforcement action. |
| Entertainment/media     | • Most of our referrals go to local law enforcement because they are more nimble to follow up and investigate cases, particularly smaller ones. We do not refer cases to federal investigators that we don’t feel are worth federal resources.  
|                         | • CBP does well when and where it can with regards to IP enforcement. Five years ago, our relationship with them was pretty good, but they have fewer resources now. |
| Luxury goods/apparel    | • Communication with CBP is not consistent. One company is still trying to understand how CBP detects IP violations.                           |
| Internet                | • We work very closely with state and local law enforcement and coordinate with federal agencies on specific investigative matters, such as CBP checking corporate shipments at ports or companies providing information for federal cases on an ongoing basis. |
| Pharmaceutical          | • We have forged effective partnerships with law enforcement agencies, including providing referrals, support to the investigating agency and assistance in determining the authenticity of products suspected as counterfeit. We note that the good working relationship that exists in New York between ICE, the FBI and the FDA is one to be emulated.  
|                         | • We will work with any law enforcement agency that can develop strong IP cases leading to successful criminal prosecutions. |
| Software                | • We coordinate some with local law enforcement on IP cases that can be completed more quickly through the local systems or that do not warrant federal attention and resources. |
Appendix III: Private Sector Views on Federal IP Enforcement Efforts

Sector: Manufacturing  
Comments:
- Our experience to date with CBP has not been very successful. The key to success would be a closer business relationship. Some companies we represent are still developing relationships with federal agencies.
- We have not had much success with CBP. Counterfeit auto parts are coming to the United States but not being stopped. Ten years ago the counterfeit packaging was poor...but now packaging is sophisticated and it is harder to detect real from fake.

Source: GAO analysis of private sector responses.

Industry Has Cited Some IP Enforcement Improvements Following Training Provided to Agency Officials

Several of the company representatives commented that increased training efforts for federal officials that carry out IP enforcement have strengthened IP enforcement efforts. Table 7 highlights private sector comments on this issue.

### Table 7: Summary of Industry Representatives’ Views on Effectiveness of Training on IP Enforcement Activity, by Sector

<table>
<thead>
<tr>
<th>Sector</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Luxury goods/apparel</td>
<td>After we provide training to federal law enforcement officials, we do see a momentary increase in action by federal law enforcement agencies. We also participate in industry seminars to stay up to date on investigation methods and remedies offered to us. This improves our ability to better coordinate our efforts with federal law enforcement on anti-counterfeiting investigations.</td>
</tr>
<tr>
<td>Internet</td>
<td>Training has certainly increased the level of cooperation and number of instances where we were able to pursue a prosecution. Just having someone to call or put together a package of supporting evidence can make a difference in whether a case will be prosecuted.</td>
</tr>
</tbody>
</table>
| Pharmaceutical          | Participating in training programs sponsored by federal agencies or private associations provides us with an opportunity to network and exchange intelligence information with representatives of other pharmaceutical companies and law enforcement officials who are also engaged in the battle against counterfeit pharmaceuticals.  
                          | It appears that a number of seizures have occurred since private sector led training with federal officials has taken place and the level of communication has increased with CBP officials at those ports. |
| Software                | Training provided to federal officials by industry has heightened awareness and helped to establish relationships between CBP port officials and companies.                                                   |

Source: GAO analysis of private sector responses.

Increased Training and Consumer Awareness Cited as Areas for Improved IP Enforcement

Industry representatives cited various areas that could be improved upon to increase overall IP enforcement, including a need to better train federal prosecutors and better inform consumers about the risks posed from counterfeit and pirated goods. Table 8 highlights areas private sector representatives identified for improved IP enforcement.
### Table 8: Summary of Industry Representatives’ Views on Areas for Improved IP Enforcement, by Sector

<table>
<thead>
<tr>
<th>Sector</th>
<th>Comments</th>
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</table>
| Consumer electronics    | • If DOJ or some other federal agency were able to facilitate contacts with local law enforcement through periodic seminars or national conferences, it would be very helpful...A good coordinating body would enable that to be done more effectively. It would ensure members know the tools and resources available.  
• To improve CBP seizures, there should be industry specific training and better communication between CBP and industry.  
• Federal prosecutors need more training on IP crimes so that they understand the nature of the problem and feel more comfortable prosecuting cases. |
| Entertainment/media     | • It would be great if we could follow the “status” of the seizure. There is no central place to get updated on enforcement actions, so one has to chase the CBP inspector. We get Notice of Seizure letters but that is about it – and would like to get “the number of widgets” in those seizure notices.  
• Federal prosecutors and judges need more training...Judges don't want to hear from rights holders. Often times they need to understand the economic impact of these crimes. |
| Luxury goods/apparel    | • More consumer awareness is needed, such as education by the media. If government and television, radio, and print journalists developed a passion for this issue, demand for counterfeit goods would be reduced. It is also important to educate consumers on the ills of counterfeiting such as child labor laws, tax evasion, and the support of terrorism. We also would recommend that companies write to government officials and supervising officers when officers or agents make a large seizure of counterfeit goods expressing appreciation and pointing out the good work accomplished by defeating counterfeiting.  
• We would like to have a better understanding of the problem from a brand perspective as well as a better understanding of the laws and how to work with the prosecuting attorneys at both the state and federal level. We would also like to see more dedicated federal resources. |
| Health/food             | • We would like to see an increase in the amount of federal penalties assessed and collected.  
• We recommend increased resources for CBP, as it is the country’s first line of defense against counterfeit products. The federal penalties on the criminal side are generally satisfactory, but we want them to be more punitive. We want federal laws enforced with more resources. |
| Internet                | • There is a need for increased cooperation and transparency in how federal agencies work together and with industry.  
• There is a need for strengthened information-sharing and communication between industry and federal law enforcement.  
• There is a need for continued training and education of federal law enforcement officials on issues specific to industry. |
## Appendix III: Private Sector Views on Federal IP Enforcement Efforts

<table>
<thead>
<tr>
<th>Sector</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Pharmaceutical | - Federal programs that encourage transportation, customs brokers, and forwarding and express companies to cooperate in the identification of potential counterfeit traffickers would be helpful. The application of targeting approaches used for anti-terrorism will help CBP to be more effective in identifying high-risk transactions.  
  - We would like to see more coordinated communication and dialogue with the pharmaceutical industry on the part of federal government.  
  - The growth of the Internet complicates law enforcement efforts, both in the United States and abroad. Federal law enforcement agencies will need to be well prepared to address two types of counterfeiting threats that may evolve in multiple and complex ways: first, agencies must deter and stop sophisticated and organized counterfeiters that prey on patients in an effort to profit from unsuspecting consumers; second, officials must be prepared to manage threats from counterfeiters who may be motivated by an intent to harm people (e.g., terrorist activity)...It is critical that federal agencies, including the Departments of Justice and Commerce and the U.S. Trade Representative’s office, make IP infringement and counterfeit activity top priorities. This effort must call for more criminal prosecutions, stiffer penalties and asset seizures. All of these activities will necessitate increased and dedicated human and financial resources. |
| Software   | - FBI’s Cyber Crime squad in Los Angeles is doing great work; however, IP should be made a higher priority for other law enforcement agencies. Positive partnerships are imperative for successful IP protection and enforcement.  
  - To improve border enforcement, federal agencies need more investigators on the job. The current amount of staff are sorely overworked. For high-tech goods, law enforcement needs more and better equipment because they currently use slow, clunky technology to go after the best and brightest cyber criminals. |
| Manufacturing | - Simply recording one’s product with CBP does not guarantee that seizures will be made of goods that infringe on the recorded product. Companies have to be proactive about protecting their products in other ways.  
  - There needs to be strengthened communication and better information sharing between industry and federal government so that enforcement efforts are more focused.  
  - There should be an effort to reduce the federal financial burden of protecting IP, such as more information-sharing within the private sector and with agencies and more collaborative enforcement efforts.  
  - There is a need for increased educational awareness for both federal agencies and industry on how to work together. There is also a need to increase consumer awareness of counterfeit parts. |

Source: GAO analysis of private sector responses.
Appendix IV: Comments from the Department of Homeland Security

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

February 26, 2008

Mr. Loren Yager
Director
International Affairs and Trade
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Yager:

Thank you for the opportunity to review and comment on the Government Accountability Office’s (GAO’s) draft report GAO-08-157 entitled INTELLECTUAL PROPERTY: Federal Enforcement Has Generally Increased, but Assessing Performance Could Strengthen Law Enforcement Efforts.

U.S. Customs and Border Protection (CBP) provided the following general comments on the report. Technical comments have been provided under separate cover.

First, the report acknowledges the enforcement priority that CBP places on stopping imports of Intellectual Property-related (IPR) violative goods that pose risks to public health and safety. However, the report inaccurately, and repeatedly, states that CBP lacks the data and definitions for IPR-related enforcement efforts that impact public health and safety. In fact, CBP defines, collects, and reports such data, and published this data in its publicly-available Fiscal Year (FY) 2007 IPR Seizure Statistics. Regrettably, GAO never specifically asked CBP to provide this data.

GAO recommends that CBP “create a category and definition for seizures of counterfeit goods that pose a risk to public health and safety of the American people, and collect and report this data throughout the agency and to Congress.” CBP will report this information to CBP’s Directors, Field Operations (DFOs) and to Congress on a semi-annual basis, and will continue to publish this data. CBP will also continue to track and analyze this data and IPR seizure data in general, and report this analysis to upper management for use in their decision-making processes.

Second, the report states several times that CBP lacks performance measures for IPR, but this is not completely accurate. CBP’s National IPR Trade Strategy, which was previously provided to GAO, contains performance measures for IPR, and it is this strategy that guides CBP’s IPR enforcement efforts. This document includes clear performance measures and targets that are directly linked to the goals and objectives of the National IPR Trade Strategy.

See comment 1.

See comment 2.
Appendix IV: Comments from the Department of Homeland Security

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CBP acknowledges that the CBP Strategic Plan does not contain specific measures for IPR enforcement, and CBP is in the process of drafting IPR enforcement measures for proposed inclusion in the Strategic Plan. CBP will report key measures and an assessment of CBP’s performance of these measures to Congress and the National Intellectual Property Law Enforcement Coordination Council (NIPLECC).

Third, throughout the report, GAO continues to promote a simple analysis of seizure outcomes among ports as the key approach for improving IPR enforcement at the border. GAO used this same approach in its most recent report on CBP’s IPR enforcement efforts, “INTELLECTUAL PROPERTY Better Data Analysis and Integration Could Help U.S. Customs and Border Protection Improve Border Enforcement Efforts” (GAO-07-350). We continue to stand by our position, as we did in our comments to the previous report, that this approach has fundamental flaws because of differences in the nature of imports among ports. GAO’s analysis inaccurately assumes relative homogeneity among “IP-type” imports at various ports. As we noted in our comments on the previous report, a fundamental flaw with this approach is that it fails to recognize relative risk and assumes that all similar commodities form a universe at equal risk for IP infringement. Further, many factors in addition to product type affect IPR risk, and these factors cannot be accounted for in this type of analysis. Such factors include source country, shipping patterns, and shipments entered by rights holders and their licensees. For these reasons, CBP finds GAO’s analysis about IPR border enforcement to be incomplete and unreliable as a basis for action to improve enforcement or allocate resources.

With respect to the recommendations addressed to CBP:

Recommendation: Create a category and definition for seizures of counterfeit goods that pose a risk to public health and safety of the American people, and collect and report this data throughout the agency and to Congress.

CBP Response: Concur. The Office of International Trade (OT) has identified categories of merchandise that could cause potential harm and included those category breakouts in the published FY07 stats. OT will provide this information to the Directors, Field Operations (DFOs) within CBP and to Congress on a semi-annual basis. September 2008 is the anticipated completion date.

Recommendation: Establish performance measures and targets for IP-related enforcement activity and report measures, targets, and performance to Congress and NIPLECC.

CBP Response: Concur. CBP will revise its performance measures and targets related to IP enforcement. In addition, OT will report key measures and performance to Congress and NIPLECC. December 2008 is the expected completion date.

Recommendation: To better inform Congress and affected rights holders regarding its enforcement of exclusion orders and address certain procedural weaknesses, we recommend that the CBP Commissioner direct the Offices of International Trade and Field Operations take the following three actions:
3

a) identify factors currently limiting their enforcement capabilities and develop a
strategy for addressing those limitations along with a timeline for implementing
the strategy;
b) begin collecting data on the number of exclusions, in total and per exclusion order;
and
c) examine CBP’s ability to develop regulations to allow notification of exclusions to
affected rights holders, and if authorized, develop such regulations.

**CBP Response:** Concur. CBP has begun to identify factors currently limiting our
enforcement capabilities on exclusion orders and will implement a strategy to address our
limitations. OT will begin tracking the number of denials of entry related to each exclusion
order and report the aggregate totals by exclusion order in the end of year IPR statistics. In
addition, OT will research CBP’s legal authority on providing affected rights holders
notification of denials of entry. CBP expects to complete these actions by September 2008.

With respect to the recommendations directed to ICE:

**Recommendation:** Analyze enforcement statistics to better understand variations in
enforcement activity.

**ICE Response:** Concur. ICE will analyze its Intellectual Property Rights enforcement data to
better understand variations in enforcement activities. This analysis will be conducted during
Fiscal Year 2008.

**Recommendation:** Create a category and definition for IP enforcement actions that pose a
risk to public health and safety of the American people, and collect and report this data
throughout each agency and to Congress.

**ICE Response:** Concur. ICE will ensure its law enforcement information system is updated to
include a narrowly defined high-risk category to categorize those enforcement actions that
focus on criminal IP violations that threaten public health and safety.

**Recommendation:** Establish performance measures and targets for IP-related enforcement
activity and report measures, targets, and performance to Congress and the National
Intellectual Property Law Enforcement Coordination Center.

**ICE Response:** Concur. ICE will begin developing IP performance metrics and measures
during Fiscal Year 2008, then report the measures, targets and performance to Congress
through an update to GAO. ICE will provide a copy of the update to the NIPLECC

With respect to the recommendation directed to the Department:

**Recommendation:** To clarify the mission and structure of the National Intellectual Property
Rights Coordination Center, we recommend that the Attorney General and the Secretary of
Homeland Security, in consultation with NIPLECC, should direct their IP enforcement
agencies to take the following three actions:
Appendix IV: Comments from the Department of Homeland Security

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- reassess the National Intellectual Property Rights Coordination Center’s mission, and how its future performance will be assessed;
- define agencies’ role in the center and the number and types of resources needed to operate the center; and
- report to Congress on the center’s redefined purpose, operations, required resources, and progress within one year of the center’s relocation.

**Response:** The Department concurs with the recommendation for the National Intellectual Property Rights Coordination Center and plans to discuss with DOJ, in consultation with NIPLECC, the expanded mission of the Center. The Department has committed 9 FTEs to the staffing of this Center which is scheduled to relocate to Crystal City in March 2008.

Thank you again for the opportunity to comment on this draft report and we look forward to working with you on future homeland security issues.

Sincerely,

[Signature]

Steven J. Pecinovsky
Director
Departmental Audit Liaison Office
The following are GAO's comments on the Department of Homeland Security's letter dated February 26, 2008.

GAO Comments

1. We discussed health and safety issues with CBP during our review. In January 2008, CBP released seizure data for fiscal year 2007 that for the first time identified seizures in product categories that may involve public health and safety, e.g., pharmaceuticals, electrical articles, and sunglasses. We commend CBP for taking this step and modified our report to reflect this new data (see p. 33). These data are publicly available; therefore, GAO did not have to request them from CBP. We added information to the draft report to state that CBP officials also told us that creating a definition of IP seizures that affect public health and safety is difficult because not all products within a given category necessarily pose such risks and the potential for such risks cuts across a broad range of products (see pp. 33-34). We modified our recommendation to state that CBP should continue to take steps toward better identifying IP seizures that pose a risk to public health and safety of the American people, and collect and report this data throughout the agency and to Congress (see p. 43).

2. We reported on CBP’s IP Rights Trade Strategy (a document that CBP refers to in its letter as the National IPR Trade Strategy) in our April 2007 report.\(^1\) We added information to this report to describe this trade strategy and note that it contains certain measures and indicators related to IP enforcement (see p. 34.) However, we also noted, as we did in our April 2007 report, that CBP officials told us this trade strategy was an internal planning document, and we determined it had limited distribution across CBP. For example, we found that revisions to the document had not been distributed to CBP ports since 2003 and given the document’s status as “For Official Use Only,” it is not distributed to Congress or the public. Therefore, we concluded in April 2007 that this document, while containing certain measures and indicators, has limited usefulness for holding CBP accountable for its performance on IP enforcement. At that time, we recommended that CBP work with OMB to include IP enforcement-related measures in its strategic plan and are pleased that CBP states in its current comment letter that it is in the process of taking such action.

\(^1\)GAO-07-735.
3. We do not understand why CBP is making comments in this report about analysis that appeared in our April 2007 report, but that is not reproduced in this report. That analysis showed that among the top 25 IP-importing ports in fiscal year 2005, many ports’ IP seizure rates (measured by value of IP seizures over value of IP imports) were lower than the group average. We did this analysis because CBP had not attempted to analyze its IP enforcement outcomes in this way. CBP made these same comments in April 2007; we disagreed with how CBP characterized our work at that time and continue to stand by our analysis. In that report, we said that this and other types of analysis contained in our April 2007 report represented approaches that CBP could take to better understand variations in IP enforcement outcomes across ports, inform resource allocations and management decisions, and further improve its IP enforcement. We continue to believe that CBP, and the other agencies, can better use existing data to understand their IP enforcement outcomes across field locations or product types as a way of further improving overall IP enforcement.

4. See comment 1.
Appendix V: Comments from the Department of Justice

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

U.S. Department of Justice

Washington, D.C. 20530

FEB 21 2008

Ms. Christine Broderick
Assistant Director
International Affairs and Trade
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Broderick:

On February 5, 2008, you provided the Department of Justice (DOJ or Department) with a copy of the General Accountability Office (GAO) draft report entitled Intellectual Property: Federal Enforcement Has Generally Increased, but Assessing Performance Could Strengthen Law Enforcement Efforts (08-157, Job Code 320471)(Report). The Department of Justice appreciates the time and effort put into this draft Report by GAO staff, as well as the professional courtesy you extended. We appreciate the opportunity to comment on the draft. In that regard, DOJ has objections and concerns with the report’s findings.

A. The Report Understates DOJ Enforcement Activity

First, although the Report acknowledges "general increases" in enforcement activity by all agencies in recent years, it severely understates the recent increases in enforcement production by the Department of Justice since FY 2004—that is, the year in which the Task Force on Intellectual Property began its aggressive work to improve the Department’s IP enforcement program in all phases. The number of defendants charged with IP offenses increased dramatically from FY 2004 (177) to FY 2006 (339)—an increase of more than 90 percent. This increase can be attributed, at least in part, to the Department’s increased emphasis on multi-district and international prosecutions, which in turn led to more multi-defendant cases. Even with the increase in multi-defendant cases, the number of cases themselves also increased substantially, by more than 20 percent—from 169 in FY 2005 to 204 in to FY 2006. To be fair, these kinds of enforcement results deserve better than a watered-down characterization as "general increases."

Moreover, the significant increases in prosecutions by the Department continued into FY 2007. For example, 287 defendants were sentenced on intellectual property charges in FY 2007, representing a 35 percent increase over FY 2006 (213) and a 92 percent increase over FY 2005 (149). In addition, case filings also continued to increase: the Department filed 217 intellectual
property cases in FY 2007, representing a 33 percent increase over cases reported in FY 2005 (169). See, Table 1, below.

The Report also fails to adequately acknowledge the significant increase in training and resource allocation accomplished by the Department since 2001. For instance, in January 2001, there was only one CHIP Unit in the United States, in San Jose, California. Subsequent expansions that year, as well as in 2002, 2005, and 2006 have increased the total number of CHIP Units nationwide to 25. These Units consist of between two and eight Assistant U.S. Attorneys who receive specialized training annually in prosecuting intellectual property and computer crimes. See, Tables II and III, below.
Appendix V: Comments from the Department of Justice

Table III

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Judicial Districts Where CHIPs Units Installed</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>NDCA</td>
</tr>
<tr>
<td>2001</td>
<td>CDCA; SDCA; NDGA; DMA; EDNY; SDNY; NDTX; EDVA; NEWA</td>
</tr>
<tr>
<td>2002</td>
<td>WDMD; NDOL; SDPL</td>
</tr>
<tr>
<td>2003</td>
<td></td>
</tr>
<tr>
<td>2004</td>
<td>EDCA; MDPL; WDPA; DCC; MDTH</td>
</tr>
<tr>
<td>2005</td>
<td></td>
</tr>
<tr>
<td>2006</td>
<td>WDTX; DMD; DCO; EDM; DMP; OCT; EDPA</td>
</tr>
</tbody>
</table>

The growth of the CHIP Unit program reflects the Department’s deep commitment to the prosecution of intellectual property and computer crimes, and it has resulted in tangible increases in prosecution successes. For example, in FY 2007, CHIP Units were responsible for sentencing 199 defendants for IP offenses, which represents an 80 percent increase over the 110 defendants sentenced in CHIP Unit districts in 2006.

Statistics alone are insufficient to accurately show the quality of improvements in the Department’s prosecution activity. For instance, there have been numerous groundbreaking investigations and prosecutions during the past year, including:

- **Three Indicted and Arrested in One of Largest Counterfeit Goods Prosecutions in U.S. History** On January 16, 2008, in Richmond, Virginia, a seven-count indictment was unsealed in one of the largest counterfeit goods prosecutions in U.S. history. The indictment charges three individuals with one count of conspiracy to traffic in counterfeit goods imported from the People’s Republic of China (PRC), four counts of trafficking in counterfeit handbags, wallets, purses, and carry-on bags, and two counts of illegally smuggling counterfeit goods into the United States. ICE agents arrested the three defendants and executed a court order restraining defendants’ numerous assets, including 29 bank accounts and three properties in New York. According to the indictment, the three defendants operated a massive international import and wholesale counterfeit goods business from 2002 until at least Oct. 31, 2005, engaging in a corporate shell game whereby they conspired to, and in fact imported, over 300,000 counterfeit luxury handbags and wallets into the United States from the PRC in the names of different companies, all under their control. The value of the corresponding authentic luxury goods manufactured by Burberry, Louis Vuitton, Gucci, Coach, and others, whose legitimate sales were displaced, is estimated to be over $100 million.
Appendix V: Comments from the Department of Justice

Ms. Christine Broderick

• **Largest Ever Joint U.S.-China Criminal Enforcement Operation Nets 25 Arrests and Over $500 Million in Counterfeit Software.** On July 23, 2007, Chinese officials arrested 25 Chinese nationals and seized more than half a billion dollars worth of counterfeit software as a result of the largest ever joint investigation conducted by the FBI and the People’s Republic of China, code-named Operation Summer Solstice.” China’s Ministry of Public Security also searched multiple businesses and residential locations, seized more than $7 million in assets, and confiscated over 290,000 counterfeit software CDs and Certificates of Authenticity.

• **First Ever Extradition for Online Software Piracy / Extradited Australian Ringleader Sentenced to 51 Months in Prison:** On June 22, 2007, in Alexandria Virginia, Hew Raymond Griffiths was sentenced to 51 months in prison for crimes committed as leader of one of the oldest and most renowned Internet software piracy groups worldwide, known as “Drink Or Die.” From his home in Australia, Griffiths violated the criminal copyright laws of the United States by leading this criminal group which caused the illegal reproduction and distribution of more than $50 million worth of software, movies, games and music. This was one of the first ever extraditions for an intellectual property offense.

• **50th Conviction in Largest Online Software Piracy Enforcement Action:** On May 14, 2007, in Alexandria Virginia, the Department obtained the 50th conviction in Operation FastLink, the largest and most successful global online piracy enforcement initiative ever conducted. This Operation culminated in the execution of more than 120 searches and arrests in 12 countries, the seizure of more than 200 computers, the complete dismantlement of 30 Internet distribution sites, and the confiscation of hundreds of thousands of counterfeit software titles valued at more than $50 million. This 50th conviction represented a milestone never before achieved in an online piracy prosecution.

B. **DOJ Has Appropriately Analyzed Its Enforcement Statistics**

The Report concludes that the federal enforcement agencies – including DOJ – have done little “to systematically examine enforcement statistics.” Report at 40. As one example of this type of systematic analysis, the Report analyzed the number of cases filed by U.S. Attorney’s Offices by district and concluded that there was a “high correlation between IP enforcement activity and offices with resources dedicated to IP enforcement.” Report at 41.

It is simply inaccurate to state that DOJ does not analyze its prosecution statistics, much less that it does not analyze them by district. We conduct such analysis routinely, and that analysis has helped inform the placement of additional CHIP Units around the country. Indeed, one of the IP Task Force’s principal recommendations in its 2004 Report was to increase resource allocations to CHIP Units in key regions.
Appendix V: Comments from the Department of Justice

Ms. Christine Broderick

"The Department of Justice should reinforce and expand existing CHIP Units located in key regions where intellectual property offenses have increased, and where the CHIP Units have effectively developed programs to prosecute CHIP-related cases, coordinate law enforcement activity, and promote public awareness programs."

The Department implemented this recommendation in January 2005, after a thorough assessment of CHIP Unit production nationwide, including analysis of case statistics by district. The Attorney General provided additional, full-time funding for a total of three AUSAs to serve as CHIP prosecutors in the Central and Northern District of California. Time has shown the wisdom of that decision: in FY 2006, the CHIP Units in the Northern and Central Districts of California charged a total of 50 IP cases, out of a nationwide total of 204 IP cases, accounting for approximately 25 percent of the national total.

Additionally, the Department considered case filings by district when it determined the locations of the 12 additional CHIP Units established since 2004, and it will continue to evaluate the need for additional CHIP Units in districts with a high incidence of IP and computer crime, or where additional prosecutors are best matched to local investigative resources.

Although the Department does routinely conduct this type of statistical analyses to identify trends in domestic IP crime, we would not necessarily draw the same absolute conclusion that the GAO staff apparently reached – i.e., that more prosecutors in a district results in more prosecutions (and the underlying assumption that IP crime occurs at the same rate and magnitude in all districts). Report at 41. It is true that some of the largest CHIP Units, such as in the Central District of California (8 prosecutors) are also the most active in terms of IP case filings. But that is because, at least in part, the Department has tried to establish CHIP Units in areas of greater criminal activity (IP or cybercrime), and has allocated additional resources to those U.S. Attorneys Offices, like Los Angeles, that are most active, receive more case referrals, and/or have the highest level of commitment from local investigative agencies.

C. DOJ Has Established Appropriate Performance Measures and Goals to Assess Its Progress

The Report suggests in numerous places that DOJ has not established performance measures or goals that adequately assess its achievements. This is inaccurate. The Department has taken unprecedented steps to assess its achievements in the area of intellectual property enforcement. It has been especially aggressive in providing progress reports on the implementation of the 31 recommendations issued by its Task Force on Intellectual Property in 2004. This includes the Task Force’s Progress Report in June 2006, as well as its annual reporting to the President and
Appendix V: Comments from the Department of Justice

See comment 9.

Ms. Christine Broderick

Congress as part of NIPLECC. See, e.g., “Report to the President and Congress on Coordination of Intellectual Property Enforcement and Protection” (January 2008). These reports can be accessed online through the following links:

2007 NIPLECC Rept (Jan 2008):

http://crmln05.crm.doi.gov/7778/pls/portal/docs/PAGE/CRIMLINK/PRESS_ROOM/PRESS_R RELEASES/YR2008/01/012008-NIPLECCRPRT.PDF

2006 NIPLECC Report (Sept 2006):


The above reports are replete with performance measures and goals. The DOJ has aggressively and thoroughly monitored its performance with respect to improving IP criminal enforcement. For example, the IP Task Force issued a detailed Progress Report in June 2006, providing extensive detail on which of its 31 recommendations had been implemented, and on which implementation was still ongoing. The Task Force has continued to set ambitious goals and objectives, and evaluate their achievement, on an annual basis. No other federal agency has been more aggressive in reviewing and improving its IP enforcement programs as the DOJ in the past few years, nor has any agency been more thorough in rating its progress and performance.

What the Department of Justice’s IP Task Force did not do, however, was set performance measures based on case quotas, numerical thresholds, or percentage “targets.” The GAO views the absence of such numerical or percentage targets as a deficiency. The Department views it as a necessity.

The GAO criticism reflects a failure to appreciate the core justice principle that criminal prosecutions should never be initiated -- or judged -- based on actuarial tables or case quotas. As the GAO Report notes, many of the Task Force’s recommendations called for “more” enforcement in critical areas, such as increases in the number and quality of prosecutions. As noted above, the DOJ achieved these goals with substantial increases in prosecution activity. For instance, in FY 2006, 213 defendants were sentenced on intellectual property charges, representing nearly 50 percent increase over FY 2005 (149). Moreover, in FY 2005, 350 defendants were charged with intellectual property offenses, nearly double the 177 defendants charged in FY 2004 – representing a 98 percent increase.
Appendix V: Comments from the Department of Justice

Ms. Christine Broderick

The GAO report discounts these substantial increases because “without [numeric or percentage] measures or targets, it is not clear how certain achievements, such as increases in arrests or numbers of defendants charged with IP crimes, should be assessed because it is not clear what the agencies sought to achieve.” Report at 43. As we attempted to explain in meetings with GAO drafters, however, the Department of Justice has intentionally resisted setting numeric or percentage “targets” as performance measures because it creates a risk that prosecutions could be initiated – or at least could be perceived as having been initiated – for the improper purpose of meeting prosecution quotas or the expectations of White House and Congressional officials.

Federal prosecutors file criminal charges based on the individual merits of each case, and only where the prosecutor “believes that the person's conduct constitutes a Federal offense and that the admissible evidence will probably be sufficient to obtain and sustain a conviction.” U.S. Attorney’s Manual 9-27.220. Criminal actions should never be motivated by prosecution quotas or numerical/percentage goals, nor should the Department risk creating an appearance of improper motivation by setting this particular types of performance measure. There are other ways to assess performance. Indeed, the Department believes that doubling the number of defendants charged with IP crimes within a one year period, or increasing by 50 percent the number of defendants sentenced, are commendable results using any performance measure. They should not be discounted simply because the Department declined to set a specific numerical or percentage “target.”

Thank you for the opportunity to submit our formal comments for inclusion in the final Report. The Department of Justice is committed to improving its intellectual property enforcement efforts, and we share with you the belief that accountability to the public and Congress are an important component of our law enforcement mission.

Sincerely,

Michael A. Atman

Lee J. Loitthus
Assistant Attorney General
for Administration

See comment 10.
### GLOSSARY OF JUDICIAL DISTRICTS
WITH CHIP UNITS INSTALLED

<table>
<thead>
<tr>
<th>Judicial District</th>
<th>Abbreviation</th>
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<tbody>
<tr>
<td>Northern District California</td>
<td>MDCA</td>
</tr>
<tr>
<td>Central District California</td>
<td>CDCA</td>
</tr>
<tr>
<td>Southern District California</td>
<td>SDCA</td>
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<td>Northern District of Georgia</td>
<td>NDGA</td>
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<td>District of Massachusetts</td>
<td>DMA</td>
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<td>EDNY</td>
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1 In order of appearance in Table III

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Page 76  GAO-08-157  Federal IP Enforcement
The following are GAO’s comments on the Department of Justice letter dated February 21, 2008.

1. We disagree that our report severely understates DOJ’s enforcement activities. Our analysis of federal IP enforcement efforts is a systematic evaluation of trends in key agencies’ enforcement indicators over a 6-year period. Although there were fluctuations (i.e., increases and decreases) in individual indicators from year to year, we concluded that all the indicators, when taken as a whole, showed a general increase in federal IP enforcement efforts from the beginning to the end of the period examined. Moreover, we considered all indicators together because no single indicator from any one agency sufficiently reflects overall trends. The DOJ statistics we examined also showed increases and decreases during the time period. However, in its letter, DOJ selected statistics that only reflect increases, and it did so in one instance by comparing the lowest and highest levels for a given indicator, regardless of the year in which they occurred, which generated the highest possible percent increase for that indicator. We do not believe DOJ’s analysis is useful for discerning overall long-term trends.

2. Our report is based on agency data covering fiscal years 2001 through 2006. In several cases, fiscal year 2007 data became available as we were finalizing our report. However, given the challenges we faced in obtaining sufficiently reliable data from all agencies for the period we studied (see appendix I, pp. 48-51), we were unable to systematically update our data in a timely fashion to include fiscal year 2007 statistics.

3. We disagree that our report gives insufficient attention to resource increases at DOJ for IP enforcement. Our report discusses the creation and growing number of CHIP units and also notes that the number of Assistant U.S. Attorneys trained to prosecute IP cases has grown in recent years (see p. 20).

4. We agree with DOJ that statistics alone are not sufficient to accurately show the quality of improvements in IP enforcement activity. This is why we recommend that DOJ and the other agencies develop IP enforcement performance measures and targets to more systematically measure and report on their efforts. While the examples that DOJ provides of recent enforcement cases are useful illustrations of the types of enforcement activity that DOJ has undertaken, they do not provide a complete picture of DOJ’s overall efforts over time. For
example, as we state in our report, agencies including DOJ could
analyze the types of IP cases it most commonly prosecutes or could
report on the number of cases it has prosecuted involving IP crimes
that posed a health and safety risk (see p. 32).

5. In section B of its letter (pp. 4-5), DOJ addresses the issue of whether
additional IP enforcement resources necessarily result in more IP
prosecutions. On page 5 of its letter, DOJ provides information that
demonstrates a correlation between increased IP resources in two U.S.
Attorney’s Offices and the number of IP cases prosecuted by those
units, but then goes on to state that it would not necessarily conclude,
as it said GAO did, that more prosecutors in a district results in more
prosecutions. We agree that existing data across all U.S Attorney’s
Offices with CHIP units does not necessarily show a high correlation
between increased CHIP unit resources and increased IP prosecutions,
and removed this language. We modified our report to note that
various factors, including crime levels, can affect the level of IP
enforcement activity (see p. 33).

6. We modified our report to state that DOJ reviewed its data on U.S.
Attorney’s Office prosecutions when deciding where to place
additional CHIP units. However, at no time during this audit did DOJ
indicate, or provide documentation reflecting, that it routinely
analyzed IP prosecution data by district. We commend DOJ for
examining the fiscal year 2006 IP enforcement activity of two of the
CHIP units. Our analysis of DOJ’s data on IP enforcement activity by
all 94 U.S. Attorney’s Offices showed a mix of activity among field
offices across the 6-year period, including those with CHIP units. We
believe that conducting such analysis on a more systematic basis can
better inform DOJ about whether its allocation of resources is
appropriate and not just inform placement of CHIP units.

7. See comment 5.

8. We mentioned in the draft report, under our discussion of agency
priorities that DOJ has established some goals related to its IP
enforcement efforts that are contained in an internal agency document
not available to the public (see p. 15). We added information to refer
again to this in our discussion of performance measures (see p. 35).
However, we disagree that DOJ’s Task Force report is replete with
goals and measures. The Task Force report makes multiple
recommendations for improving IP enforcement efforts, but
recommendations are not the same as performance goals, and the
report does not contain performance measures. Moreover, many of
these recommendations are task-oriented actions rather than outcome-
oriented. For example, one of DOJ’s Task Force recommendations is to prosecute aggressively intellectual property offenses that endanger the public’s health or safety; yet, DOJ does not provide any details on how they plan to achieve this recommendation and how they will measure their progress. Further, as we report, DOJ has not taken steps to capture enforcement statistics to assess their progress in this area. As we discuss in our report, strategic planning and assessment requires agencies to articulate outcome-oriented goals and objectives and to develop performance measures and targets that will enable them and others to determine whether they are making progress toward these goals. We added language to our report to better define outcome-oriented performance measures.

9. We added information to the report to further explain the challenges associated with setting performance measures and targets in the law enforcement area (see p. 35). Our example of a performance measure and target was not intended to suggest that the agencies should adopt numerical case quotas or take any steps that would otherwise negatively affect the quality of their investigations. However, because it was interpreted in this way, and distracted attention from the more important discussion of adopting appropriate performance measures and targets, we removed the example. We continue to believe that DOJ can develop reasonable and acceptable measures and targets for IP enforcement.

10. See comments 1 and 4.
Appendix VI: Comments from the Department of Health and Human Services

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary for Legislation

Washington, D.C. 20201

FEB 9 2008

Loren Yager
Director, International Affairs and Trade
U.S. Government Accountability Office
Washington, DC 20548

Dear Mr. Yager:


The Department appreciates the opportunity to review and comment on this report before its publication.

Sincerely,

Vince Ventriggia
Assistant Secretary for Legislation
Appendix VI: Comments from the Department of Health and Human Services

GENERAL COMMENTS OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT ENTITLED: "INTELLECTUAL PROPERTY: FEDERAL ENFORCEMENT HAS GENERALLY INCREASED, BUT ASSESSING PERFORMANCE COULD STRENGTHEN LAW ENFORCEMENT EFFORTS" (GAO-08-157)

See comment 1.

The Department does not agree with GAO’s recommendation to “establish performance measures and targets for IP-related enforcement activity and report measures, targets, and performance to Congress and NIPLECC.” As GAO notes, such measures and targets are difficult to establish in the law enforcement arena. For FDA, such measures and targets would not be meaningful, would be difficult to set, and might even be counterproductive.

The amount of criminal activity involving FDA-regulated products cannot be known in advance, or accurately predicted, for any given year. More specifically, the universe of potential cases cannot be accurately identified, making it difficult to set performance measures for their investigation.

In its report, GAO offers an example of a performance target for DOJ as: “... to ‘increase by ‘yy’ percent the number of prosecutions filed based on investigative agency referrals.’” FDA undertakes criminal investigations of counterfeit FDA-regulated products in response to reports and other information gathered by the agency. FDA evaluates these leads and potential cases to ascertain whether or not a full criminal investigation should be pursued. Imposing a percentage-based target might negatively affect the quality of cases brought if achievement of this percentage goal, rather than the merits of the cases, were to become a driving force for pursuing investigations.

GAO noted in its report that FDA already tracks its “achievements” regarding counterfeit FDA-regulated products. More precisely, FDA monitors the number of criminal investigations to identify any trends in product areas and to develop an understanding of the scope of counterfeiting in those areas. FDA plans to continue these monitoring efforts as a means to assess and refine our investigational approaches as appropriate. In addition, FDA collaborates, and will continue to collaborate, with other law enforcement agencies, as well as private sector entities, to advance FDA’s efforts to address counterfeit products in accordance with the agency’s mission to protect public health. However, for the reasons described above, establishing and reporting on performance measures for FDA’s conduct of criminal investigations of counterfeit FDA-regulated products would not be meaningful or feasible, and might even be counterproductive.

Therefore, the Department does not concur with GAO’s recommendation.

See comment 2.

See comment 3.
The following are GAO’s comments on the Department of Health and Human Services letter dated February 25, 2008.

1. While we acknowledged in our draft report that setting performance measures and targets in a law enforcement area is difficult, we added information to further explain why setting such measures and targets is a sensitive issue (see p. 35). We continue to believe that setting performance measures and targets is important, even in the law enforcement environment. However, because FDA’s primary mission is to protect public health and safety, we reconsidered our recommendation that FDA set law enforcement-related measures and targets, and no longer direct this particular recommendation to FDA.

2. We modified our report to provide additional information on the definition of output and outcome performance measures and targets (see p. 35). Our example of a performance measure and target was not intended to suggest that the agencies should adopt numerical case quotas or take any steps that would otherwise negatively affect the quality of their investigations. However, because it was interpreted in this way, and distracted attention from the more important discussion of adopting appropriate performance measures and targets, we removed the example.

3. We commend FDA for monitoring the number of criminal investigations to identify any trends in product areas and to develop an understanding of the scope of counterfeiting in those areas. FDA mentioned for the first time in December 2007 that it conducts such analysis, but given the challenges we faced in obtaining sufficiently reliable data from all agencies for the period we studied (see appendix I, pp 48-51), we did not ask FDA to provide this analysis to us. Given the increasing threat posed by IP-infringing products that affect public health and safety, we believe it is important that the government improves its understanding of this threat. Therefore, we modified our recommendation to ICE, FBI and DOJ that agencies conduct analysis of their IP enforcement outcomes to also address this recommendation to FDA and to clarify that such analysis should be done systematically (see p. 43).
Appendix VII: GAO Contact and Staff Acknowledgments

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<tr>
<th>GAO Contact</th>
<th>Loren Yager (202) 512-4347 or <a href="mailto:yagerl@gao.gov">yagerl@gao.gov</a></th>
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<tr>
<td>Staff</td>
<td>Christine Broderick, Assistant Director; Shirley Brothwell; and Adrienne Spahr made significant contributions to this report. Virginia Chanley, Karen Deans, Ernie Jackson, Mark Molino, Jackie Nowicki, Dimple Pajwani, Suneeti Shah, Jena Sinkfield, Stephen Caldwell, Tony DeFrank, Rebecca Gambler, Michael Simon, Tom Costa, and Jennifer Young also provided assistance.</td>
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