

## PLANNING FOR FAKES



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On June 22, 2010, the newly created executive branch office of the Intellectual Property Enforcement Coordinator (IPEC) released the first US Joint Strategic Plan on Intellectual Property Enforcement. The plan was based on information gathered from several federal agencies as well as public input on the costs and risks of IP infringement.

The plan addresses the economic concerns of IP infringement—chiefly the impact on innovation, investment and jobs amounting to billions of dollars lost to the US economy each year—and the risks to public health and safety posed by counterfeit products and the criminal activity surrounding counterfeiting operations.

The plan outlines six primary objectives, of which the following are of particular interest to rights holders and advocates:

- Increasing transparency in enforcement policy development: supporting information-sharing and reporting of law enforcement activities at home and abroad
- Enforcing US rights internationally: work with trading partners and international organisations
- Securing our supply chains: stemming the flow of infringing products at our borders.

These objectives are further detailed in more than 30 enforcement actions.

Under the plan, rights holders are urged to increase information-sharing with the government through production coding and sharing samples of goods. The plan also pledges to give federal agencies the necessary authority to share similar information with rights holders prior to and following government seizure.

With regard to imports, to strengthen enforcement under Section 337, Customs and Border Protection (CBP) and the International Trade Commission (ITC) will consider the creation of an *inter partes* ITC proceeding as part of the exclusion order enforcement process to better involve the interested parties most familiar with the scope of the IP rights and exclusion order at issue.

Additionally, the plan calls for a process whereby a party can make a voluntary disclosure to CBP when it discovers that it has unknowingly acquired counterfeit or pirated products. This would provide relief from civil enforcement actions as long as disclosure is made prior to the commencement of an investigation.

Several actions will specifically affect pharmaceutical and medical product manufacturers, importers and providers. Manufacturers and

importers will be required to notify the Food and Drug Administration (FDA) of known counterfeits of any pharmaceutical or medical product and any known health risks associated with those products. Legislation will require drug manufacturers to provide the FDA with a biannual list of all legitimate drug products in the stream of US commerce. And manufacturers, wholesalers and dispensers will be required to implement a track-and-trace system to authenticate products and create an electronic record using unique product identifiers.

Efforts to secure supply chains are also focused on cracking down on infringement stemming from foreign-based websites that provide access to counterfeit or pirated products, with a focus on Internet pharmacies. The plan calls for expanding and further publicising a list of Internet and physical markets to highlight those identified as dealing in infringing goods.

A broader goal of the plan is to achieve an increase in US exports overall through stepped-up enforcement abroad. To that end, Federal law enforcement will step up domestic investigations of foreign infringers and encourage foreign counterparts to increase criminal enforcement. There will be an increased emphasis on the US Trade Representative's 'action plans' for those countries of greatest concern in order to encourage improvements in enforcement, including through US trade agreements. Additionally, overseas personnel and improved training will be prioritised in these areas. Enforcement efforts abroad would also focus on aiding US businesses facing difficulties enforcing IP rights in overseas markets, particularly in China.

These goals are balanced by the plan's objective to implement legislative changes to give CBP authority to issue administrative penalties against infringing exports as well as imports.

Lastly, the plan's drafters were careful not to undermine the importance of 'fair use'—a concern raised in many public comments. Specifically, one of the stated actions is to include an explanation of the balance between rights and the 'fair use' limits of those rights in the training of enforcement personnel.

Many of these actions will be implemented through new or amended legislation in the coming months; interested parties will need to keep informed.

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