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# 6 Ways IP Enforcement Plan Impacts Public Health And Safety

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*Law360, New York (December 15, 2016, 10:21 AM EST)* -- Not many government reports begin with such a poetic preamble:

> A product is not less useful because it is intellectual, intangible, sometimes even invisible. It is easier to steal a song than a cow, but a musician needs to earn a living no less than a dairy farmer. The world craves new songs as much as it does fresh butter. — Dana Gioia, Poet Laureate of California.

On Dec. 12, 2016, the Office of the U.S. Intellectual Property Enforcement Coordinator (IPEC) in the Executive Office of the President issued a much-awaited interagency plan on intellectual property enforcement. The joint strategic plan on IP enforcement (fiscal year 2017 to 2019) entitled "Supporting Innovation, Creativity & Enterprise: Charting a Path Ahead" is required by law under the Prioritizing Resources and Organization for Intellectual Property Act of 2008, Pub. L. No. 110-403 (the PRO-IP Act ) which requires development of a three-year national plan on enforcement of laws protecting copyrights, patents, trademarks, trade secrets and other forms of IP, with an emphasis on combating counterfeit and other infringing goods in the domestic and international supply chains. Prior Plans were issued in 2010 and 2013.

At 163 pages in length, the plan offers a comprehensive portrait of a variety of IP violations, including counterfeit medicine, the harms they cause to patients, businesses, governments, our economy and national security, the vulnerabilities in our systems from which they arise, and, most importantly, well-considered proposals for addressing those weaknesses. The plan incorporates a range of perspectives, including stakeholders concerned about public health and safety, and establishes a new benchmark for IP enforcement efforts in the coming years.

**Why the Plan Still Matters**

Released 37 days before President-elect Donald Trump takes office and new federal government leadership takes over the many agencies and departments which developed it, the plan still matters for two key reasons:

**1. Federal law requires the plan to live on for three years.**

The PRO-IP Act requires a three-year national plan on IP enforcement. Congress mandated a three-year

cycle in an effort to encourage the development of an IP enforcement plan that will live on into future four-year administrations. This will be manifest in at least two ways:

(1) By law the plan will live on the White House website for three years, to be referenced as the federal government position on IP enforcement well into the Trump administration; and

(2) Federal agencies and departments will be held accountable as the IPEC is subject to oversight and required to submit annual reports to Congress on the federal government's implementation of the plan.

**2. The plan reflects the federal government's position, not just the views of the White House.**

The plan is not that of just one U.S. government agency or department. Rather, it represents the entire federal government's position on IP enforcement and sets forth the work to be carried out over the next three years across all agencies. This "whole of government" approach is reflected in how the plan was developed and, as discussed below, how it will be implemented.

The plan was prepared by the U.S. Interagency Strategic Planning Committees on IP Enforcement, chaired by the IPEC and comprised of a diverse array of federal divisions, including the U.S. Department of Justice, U.S. Department of Homeland Security, U.S. Department of State, U.S. Department of Commerce, U.S. Department of the Treasury, U.S. Department of Health and Human Services, U.S. Department of Agriculture, the Office of Management and Budget, the Office of the U.S. Trade Representative, and the U.S. Copyright Office.

The plan was developed also by receiving input, as appropriate, from a wide variety of additional stakeholders across the federal government and from state and local governments, industry, nongovernmental organizations, educational institutions, trade organizations, public interest groups, U.S. embassies and consulates, foreign governments, international organizations, and law enforcement bodies around the world.

**Why the Plan Matters for Patient Safety: Six Things to Know**

Counterfeit medicines — including those made available through both bricks-and-mortar and online sales channels — are discussed throughout the plan. Below are the top six things stakeholders concerned about patient safety and counterfeit medicines should know.

**1. Internet Commerce Companies and Payment Processors Continue to Have an Important Role**

For those working in digital health fields (telemedicine, online pharmacy, etc.), Section 2 of the plan is most meaningful. As called for in prior joint strategic plans, the current plan emphasizes the importance of voluntary action by payment processors, advertising providers, foreign banks, domain name registries and registrars, social media platforms, and mobile app developers. Primary among these actions is the need for companies to enforce their terms of service prohibiting use of their platforms for illegal activity, including IP crimes and illegal online pharmacies.

Section 2 of the plan makes 24 recommendations related to the digital environment, including online sales of counterfeit medicines. A few highlights include:

- Encourage enhanced transparency:

    - In the operation and effectiveness of the private-sector-led voluntary initiatives to combat revenue flow to online commercial pirates and commercial-scale traders of counterfeit goods.

    - In advertising networks to make appropriately generalized and anonymized data publicly available to permit study and analysis of illicit activity intercepted on their platforms and networks

- Encourage benchmarking studies to gauge and strengthen voluntary best practice initiatives.

- Integrate awareness of IP crime and its illicit proceeds into broader efforts to combat money laundering and the financing of transnational organized crime networks.

- Continue to assess the nature of abusive domain name registration tactics and identify opportunities to minimize criminal activity.

- Support development of best practices, through a multistakeholder process, for internet search providers to address search result rankings of significant commercial-scale piracy and counterfeiting sites.

- Encourage the development of "know your seller" programs for social media channels engaged in e-commerce. In order to minimize the exploitation of a site's services and platforms by entities engaged in the sale of counterfeit goods, social media platforms could consider requiring new sellers using the social media platform to submit to a multifactor verification system or other mechanism to support a "trusted" seller and advertiser program.

- Promote and expand U.S. law enforcement partnerships with e-commerce platforms to disrupt incidents of fraud.

**2. Consumer Education Remains Critical**

As counterfeits continue to proliferate online (see data below), consumers need to know where to turn for legitimate products, including medicines.

The plan highlights the partnership between Microsoft and the U.S. Food and Drug Administration to provide an educational pop-up when a participating search user clicks on a pharmaceutical site that has been cited by the FDA as a fake online pharmacy engaged in illegal activity, such as the sale of counterfeit drugs to U.S. consumers.

The plan recommends:

- The private sector examine opportunities for targeted consumer education on known sites that pose verifiable risks.

- Development of public-private partnerships aimed at reducing the consumer knowledge gap through appropriate education initiatives to enable consumers to make better-informed and safer online transactions.

- The U.S. government convened an interagency group to identify options to analyze online consumer behavior and identify means to promote consumer protection.

To advance consumer education, the plan requires the IPEC to convene an interagency group, including federal independent agencies such as the Consumer Product Safety Commission and the Federal Trade Commission, and other relevant stakeholders, to discuss and assess online consumer behavior to better understand threats and vulnerabilities; evaluate existing federal, state and private sector consumer education efforts; and identify opportunities for effective programs to protect consumers.

**3. The Plan Recommends Several Meaningful CBP Improvements**

The IPEC worked closely with U.S. Customs and Border Protection (CBP) to develop a number of constructive methods for enhancing the interdiction of counterfeit medicines at U.S. ports:

- Use of an "all-threats" approach to cargo screening, empowering agents involved in cargo screening programs throughout the system to treat intellectual property rights violations as threats to our national security.

- Addressing several existing loopholes in the system commonly leveraged by counterfeiters, including:

    - The ability to assemble and finish counterfeit products in-country once their harder-to-identify components have cleared customs;

    - Operational and technological inefficiencies in the screening of express shipments; and

    - The lack of advance targeting information for international mail.

- Use of a real-time IPR recordation system database, enabling rights holders to maintain current information and training materials concerning their ever-changing supply chains.

- Evaluation of the use of civil penalties and the sharing of data on known violators to optimize the deterrence of IPR and other violations. If brought to fruition, these changes would bolster patient safety and enhance rights holders' product security efforts.

**4. Proactive Engagement Beyond Our Borders Is Essential to Combat the Trade of Illicit Medicines**

The plan recognizes that the first lines of defense in the battle against illicit trade are far beyond American shores, as it:

- Shines a spotlight on the often minimal scrutiny given to goods transiting through foreign countries to other final destinations as well as to free trade zones that enable counterfeiters to mask their illegal activities.

- Underscores the importance of supporting developing countries' efforts to build modern recordation systems and of embracing the information-sharing potential of global platforms like

> the World Customs Organization's Interface Public Members (IPM) database and the United Nations' Automated System for Customs Data (ASYCUDA) intellectual property module.

U.S. government efforts to foster global transparency and communication should redound to strengthen the security of the supply chain for legitimate medicines within U.S. borders.

**5. There Is No One Silver Bullet: Stakeholders Must Work Cooperatively and Globally**

The final section of the plan connects online environment (discussed in Section 2) and the physical environment (discussed in Section 3) by examining the policies and actions that would further support robust IP enforcement worldwide. This includes recommendations on ways to improve U.S. government action as well as enhancements that could be made internationally.

Using counterfeit medicines as a case study, the plan calls for increased cooperation and capacity-building internationally:

> ...an enforcement operation organized by the World Customs Organization in partnership with the Institute of Research against Counterfeit Medicines (IRACM) (Operation Vice Grips 2) was conducted simultaneously at 16 major African seaports in July 2012, with 110 maritime containers being inspected. Of these, 84 containers (or 76 percent) "were found to contain counterfeit or illicit products," resulting in "the seizure of more than 100 million counterfeit products of all categories." These and other disproportionate effects in vulnerable markets must be addressed collaboratively by the international community, and trade policy must bridge regulatory and enforcement gaps between developed and developing economies. Page 132.

Specifically, the plan calls for the U.S. government to, among other things:

- Promote and support foreign governments' adoption of "whole of government" and "specialized office" approaches to IP rights protection and enforcement.

- Work with foreign governments as well as with regional, international and nongovernmental organizations, and industry associations to promote the "whole of government" and "specialized office" approaches as best practices for the enforcement of IP rights worldwide.

- Develop a comprehensive assessment for capacity-building and/or cooperation on IP enforcement in appropriate countries or regions and coordinate programs that are responsive to the findings of the capacity-building assessments.

- Enhance opportunities for information sharing with foreign governments.

Section 4 concludes by identifying areas where further data and research are needed to inform policy development, including research opportunities to support public health and safety.

**6. The Plan Provides Lots of Data on Counterfeit Medicines in One Place**

As evidenced in its 339 citations, the plan aggregates data, facts and case studies from hundreds of

sources. This is especially true on the counterfeit medicines issues. A few excerpts to note:

**Small Parcels:** "Small products — such as counterfeit medicines in the form of anti-malarial and anti-parasitic drugs, antibiotics and analgesics — have been found concealed inside air conditioning equipment, music speakers and sports balls." Page 29

**Online Pharmacy Distribution Network:** An infographic shows the international framework utilized by rogue internet pharmacy operators, explaining that it is "not uncommon to see complex international sales and distribution frameworks. For example, a consumer accessing a website purporting to be a "Canadian pharmacy" will in fact access one of numerous "mirror" counterfeiting sites managed from Russia, with web servers in Brazil and China, with payment processing operations run out of a bank in Azerbaijan, with bulk products shipped from India or China, transiting through Hong Kong, then sent by air to the United Arab Emirates, passing through London Heathrow Airport, and with counterfeit inventory to be finished (packaged) in the Bahamas, before being delivered to a customer in the United States or elsewhere." Page 30

**Seriousness of the Threat:** "Among all counterfeit goods, counterfeit pharmaceuticals pose one of the most serious and pervasive health and safety threats. As noted by The Economist, "[s]alesmen have peddled worthless cures for millennia. But the 21st century is turning into a golden age for bad drugs ... For criminals, fake pharma is lucrative and the penalties are usually low. Indeed, the drug supply chain is a cheat's paradise." Page 36

**Types of Medicines Faked:** "Since the launch of the World Health Organization's surveillance program in 2013, over 920 different medical products have been reported so far, representing every region of the world, affecting medical products from all main therapeutic categories, and representing both innovator and generic medicines." Page 37

**Origin of Counterfeit Medicines:** "Ninety-seven percent of all counterfeit pharmaceuticals seized at the U.S. border in FY 2015 were shipped from four economies: China, Hong Kong, India and Singapore." Page 37

**Counterfeit Controlled Substances:** "Counterfeit drugs are manufactured to closely resemble the real thing, often making it virtually impossible for consumers to detect whether the medicinal products they are ingesting are genuine or counterfeit. This can be especially dangerous if the counterfeit product appears as commonly prescribed opioid pain medication, such as oxycodone or hydrocone, yet the counterfeit actually contains illicitly produced fentanyl, a significantly more powerful synthetic opioid, because fentanyl can plunge users into overdose quickly." Page 37

**Scale of the Rogue Online Pharmacy Problem:** "With a growing number of individuals shopping online for affordable medicine, consumers are now confronted with an alarming number of rogue internet pharmacy sites. Criminal networks have become increasingly sophisticated, stocking rogue pharmacies with counterfeit medicines made all over the world and posing as legitimate pharmacies. Yet, a review by the National Association of Boards of Pharmacy (NABP) has shown that as few as three percent of websites selling prescription drugs are legitimate pharmacies." Page 37

**Use of Profits to Fuel Other Crimes:** "These [criminal] networks generate illicit profits that may be used for other criminal activities, such as drug trafficking, people smuggling, bribery, money laundering and terrorism."

**Connection to Organized Crime:** "The United Nations and other entities have similarly reported that organized criminal networks — such as the Mafia in the Americas, the Colombian and Mexican drug cartels, the Russian Mafia, the Neapolitan Camorra in Europe, and the Triads and Yakuza in Asia — have diversified into the illicit trafficking of counterfeit and pirated goods, including counterfeit medicines, luxury apparel and accessories, DVDs and CDs, and other goods." Page 43

Additionally, "… the Irish Republican Army (IRA), which has been linked to the sale of various counterfeit products, including counterfeit veterinary medicine." And "… it was widely reported that North Korea facilitated the distribution of large volumes of counterfeit pharmaceuticals and cigarettes as a means to generate hard currency due to the state of sanctions …" Page 43-44

**High Profits:** "… counterfeit medicines, for example, require no research and development and are manufactured under minimal cost, and thus enjoy profit margins reportedly as high as 3,000 percent; a $1,000 investment in counterfeit prescription drugs may result in a $30,000 return, which is 10 times the reported profit rate of trafficking heroin." Page 61

**Conclusion**

From poems to policy, proposals to practices, the plan is a bold call to action for stakeholders determined to protect our national health, economy and security from the scourge of counterfeit medicines. By setting forth the IP enforcement policy agenda for the next three years, the plan gives both public and private sector stakeholders a solid road map from which to work.

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