



1300 I Street NW, Suite 400E, Washington, D.C., 20005

Partnership for Safe Medicines (PSM)
Comments Docket No. [PTO-C-2023-0006](#)

About Us

The Partnership for Safe Medicines, a not-for-profit founded in 2003, educates healthcare professionals, law enforcement, policymakers, and the public about the risks of counterfeit medicines. Annually we conduct live continuing education courses for hundreds of pharmacists and active-duty law enforcement professionals to teach them the techniques of counterfeit medicine criminals. Through our social media channels we reach tens of thousands more.

Comprised of more than 45 non-profit organizations, The Partnership for Safe Medicines (PSM) is a public health group committed to the safety of prescription drugs and protecting consumers against counterfeit, substandard or otherwise unsafe medicines. You can learn more about PSM at www.safemedicines.org.

The use of trademark law to protect public health

Because the names and other features of many medical products are trademarked, civil trademark litigation provides a powerful weapon for rightsholders to protect patients from counterfeit (substandard) medical products. We are enthusiastic about this opportunity to share with you the important ways we see trademark protection being used to fight counterfeit medicines, and the untapped potential to use it in the future.

Shutting down enterprises that traffic in counterfeit versions of trademarked medicines

In January 2022 the world was alerted to a network of criminals who were trafficking in counterfeit HIV medications in the legitimate, licensed supply chain¹. Hundreds of millions of dollars of unsafe product was involved, and in some cases that unsafe product reached patients. Because of the magnitude of the crime and the way counterfeit medicines leave little evidence, many patients who were endangered may never know they took counterfeits.

¹ [“Drugmaker Gilead Alleges Counterfeiting Ring Sold Its HIV Drugs”](#), Wall Street Journal by Joseph Walker and Corinne Ramey, January 18, 2022

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In the case of the HIV medicines in question, they are dispensed sealed to patients, often in 30-day supply packages. Because they are dispensed as sealed, many of the pharmacists who were duped by the criminal licensed wholesalers often had no idea they were dispensing counterfeit products since they could not open up the bottles to examine the medicine without breaking the sterility seal and spoiling them.

Many medical products, including their pills, packaging, and safety literature inserts, are protected by trademark or other law. When counterfeiters make fake versions of these products and introduce them into the supply chain, they commit both criminal violations as well as civil trademark violations.

In this case, counterfeiters sometimes purchased empty bottles and filled them with random pills. They sometimes had to print missing boxes, security foil seals, shrink wrap, as well as safety literature inserts.

While we are all familiar with criminal prosecutions, the opportunity for rightsholders to enforce civilly for trademark violations is somewhat novel in the medical anti-counterfeiting space and has become a patient safety technique over the last ten years. Using the powers given to rightsholders under trademark law², the attorneys acting on behalf of trademark holders are able to conduct unannounced seizures and litigate cases under seal to prevent the perpetrators from hiding the evidence of their life-endangering crimes³.

What's more, the evidence gathered in these civil cases is readily available to law enforcement to facilitate a criminal prosecution. This is a useful public-private partnership. In the case mentioned above, two of the accused leaders of the criminal enterprise have either pled guilty or are under federal indictment^{4,5}. Over one hundred more remain embroiled in civil litigation⁶.

Infringing pill molds that mimic trademarked tablets

Trademark infringing equipment that duplicates trademarked pharmaceuticals is freely sold and used by criminals, often with deadly consequences.

² See Lanham Act, 15 U.S.C. § 1051 et seq (2012), <https://www.law.cornell.edu/uscode/text/15/1051>

³ See 15 U.S.C. § 1116 et seq, <https://www.law.cornell.edu/uscode/text/15/1116>

⁴ US v Lazaro Hernandez, Court Docket No: 22-CR-60129, Sentenced June 15, 2023, <https://www.justice.gov/criminal-vns/case/united-states-v-lazaro-hernandez>

⁵ US v Steven Diamanstein, Court Docket No: 3:23-CR-005110MAS, Indicted June 26, 2023, <https://www.justice.gov/criminal-fraud/file/1588636/download>

⁶ Gilead Sciences vs Safe Chain Solutions et al, Court Docket No: 21-cv-4106, <https://fingfx.thomsonreuters.com/gfx/legaldocs/dwpkrodwdvm/gileand-amended-2022-09-28.pdf>

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Pharmaceutical pill designs can and are trademarked. For medicines like Xanax⁷, [infringing copies are made using pill molds like this one sold openly on the clear web.](#) The machinery used to make infringing versions of pills has evolved in recent decades to be modularized enough that a manufacturer no longer needs a dedicated machine to produce a wide variety of pills out of powder mixture. Pill presses, or more specifically tableting machines, come in a wide variety of uses and target different market segments from small batch hobbyist [hand presses](#)⁸ to [industrial grade machinery](#)⁹ that can produce 180,000 pills per hour.

There are two key elements that are required to make an infringing copy of a counterfeit pill: the tableting machine that presses powder into a shape, and the pill mold (or die) that defines the shape and any imprinted design on the tablet. [PSM has published the most in-depth report to date on the prevalence of pill presses and their legal status](#)¹⁰. PSM also tracks the ongoing seizures of pill presses by law enforcement in criminal cases in this same ongoing report.

It is important to understand that tableting machines can reasonably be used for non-infringing purposes. These multipurpose items are used to make compounded medication, novelty candies, and many other uses that involve non-infringing materials. Because of this dual use, PSM does not advocate for making pill presses or tableting machines illegal.

Because of industry standardized tableting machines, it is possible to purchase pill molds in all shapes and forms from pill mold manufacturers who do not themselves make tableting machines. In fact there is an enormous market in a broad variety of pill molds for novelty tablets, generic medicines, as well as trademark-infringing tablets. Even when used to make tablets that aren't the current crop of deadly controlled substances (e.g. fentanyl), counterfeit versions of life-saving medications can be deadly. Take, as an example, these [fake blood thinners revealed by the Pharmaceutical Security Institute in January 2022](#)¹¹. These tablets are entirely placebo, they have no active pharmaceutical ingredient in them at all. Taking them when you think you are getting a blood thinner is a medically dangerous event.

⁷ DOJ/DEA fact sheet on counterfeit pills, <https://www.dea.gov/sites/default/files/2021-05/Counterfeit%20Pills%20fact%20SHEET-5-13-21-FINAL.pdf>

⁸ Demonstration video of how to use a hand pill press by manufacturer LFA Machines, <https://www.youtube.com/watch?v=fIXkIipFhFw>

⁹ Demonstration of LFA Machines RTP-41 high volume tablet press, <https://www.youtube.com/watch?v=qSJcKEddJOM>

¹⁰ Illegal Pill Presses: An Overlooked Threat To American Patients, <https://www.safemedicines.org/importation-page/illegal-pill-presses-2021-update>

¹¹ Fake Blood Thinners Found In Mexican Pharmacies, <https://www.safemedicines.org/2022/04/buying-medicine-in-mexico.html#blood-thinners>

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While a pill press has purposes for both infringing and non-infringing activity, pill molds of trademarked pills like [this Xanax mold for sale online](#)¹² have only infringing uses¹³.

Recently, we have seen trademark law used to pursue pharmaceutical counterfeiters. In Multnomah County, OR, [prosecutors are charging defendants caught selling counterfeit oxycodone M30 pills with trademark counterfeiting](#)¹⁴. Here you can see an example of an [infringing mold for this trademark pill for sale online](#)¹⁵.

Because of the multipurpose nature of pill presses, PSM has advocated a penalty-focus approach to discourage pill press usage. In short, we have endorsed legislation like U.S. House of Representatives David Kustoff (R-TN) and Abigail Spanberger's (D-VA) bipartisan bill, [H.R. 1549, the Criminalizing Abused Substance Templates \(CAST\) Act](#)¹⁶, that would escalate penalties for distribution of controlled substances if a pill press was used in the commission of a crime. This ensures that non-infringing users of pill presses do not have the legal status of their pill press activity altered unless they veer into counterfeit pill production.

Additionally Sen. Grassley (R-IA) and Sen. Coons (D-DE) recently introduced a resolution recognizing August as [National Anti-Counterfeiting and Consumer Education and Awareness Month](#)¹⁷. In the resolution they specifically reference trademark law and the powers for rightsholders to use it to protect the public.

USPTO Should Highlight This Excellent Use of Trademark Law And Support Rightsholders Who Use it

Counterfeit medical products are a danger to the public. Any method, civil or criminal, of ending counterfeit activity is a societal good. Law enforcement investigation and prosecutorial resources are now and have always been scarce. There are often more criminal infringers available than there are resources to pursue them.

¹² Custom Zp Xanax Dies 22mm Punch and Dies Zp-9 Pill Press Mold, Sales listing at ecommerce website made-in-china.com, <https://ed1e324bc81df472.en.made-in-china.com/product/FJyrRvTKHzWn/China-Custom-Zp-Xanax-Dies-22mm-Punch-and-Dies-Zp-9-Pill-Press-Mold.html>

¹³ Xanax tablets are trademarked. Registration number 1137561

¹⁴ "Multnomah County Prosecutors Are Charging Fentanyl Dealers With Counterfeiting A Big Pharma Trademark", Willamette Week, March 29 2023, <https://www.wweek.com/news/2023/03/29/multnomah-county-prosecutors-are-charging-fentanyl-dealers-with-counterfeiting-a-big-pharma-trademark/>

¹⁵ wholesale M30 stamp die TDP-0/TDP1.5TDP5/ Tablet Die Lab Supplies Candy Press Die For TDP Machine, sales listing at ecommerce platform dhgate.com, <https://www.dhgate.com/product/m30-stamp-die-tdp-0-tdp1-5tdp5-tablet-die/775270897.html>

¹⁶ HR 1549 on Congress.gov, <https://www.congress.gov/bill/118th-congress/house-bill/1549>

¹⁷ Press release on Sen. Coons official website, <https://www.coons.senate.gov/news/press-releases/senators-coons-grassley-introduce-resolution-recognizing-august-as-national-anti-counterfeiting-and-consumer-education-and-awareness-month>

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Whenever the opportunity arises to allow commercial rights holders the ability to pursue counterfeiters civilly to terminate infringing activity, we have an excellent example of public-private partnership. When the infringing material happens to be lifesaving healthcare products, such civil litigation becomes a matter of the highest value: the protection of public health.

USPTO has asked in this Request For Information about current anticounterfeiting strategies and given USPTO's mission, we assume that the intersection of trademark law and anticounterfeiting to be of particular interest.

The technique of using enforcement of trademark law to shut down illegal actors within the supply chain, as described in the above counterfeit HIV case, is a technique that is not yet widely adopted or widely known. We believe protecting patients from counterfeit medicines using trademark law is an important social good that deserves highlighting. There are currently success stories that many can learn from to conduct their own patient safety programs.

We find the market for pill molds for sale online to be particularly poorly regulated and few, if any, success stories exist. PSM hopes that there is potential for using trademark law to help shut down sellers of infringing devices such as pill molds for trademark pills. PSM would be excited to help raise awareness of the potential to use trademark law to reduce the availability of illegal pill molds online.

There are other stakeholders who could provide input on these issues, including:

- Rightsholders counsel both inside and outside counsel¹⁸;
- Law enforcement at the federal and state level who have brought “follow on” criminal charges in the wake of civil trademark enforcement actions;
- Manufacturers of pill presses and if reachable, sellers of pill molds; and
- Business service providers, particularly online providers, of marketplaces that sell infringing pill molds.

The Partnership for Safe Medicines would be happy to assist USPTO staff with any inquiries into this arena. We remain excited about the work being done today to use trademark law to protect American patients from counterfeit medicines. You can reach us through Executive Director Shabbir Imber Safdar at shabbir@safemedicines.org or our Federal Affairs Consultant, Stacey Barrack at SBarrack@ventureglobal.com.

¹⁸ Some of the most high profile trademark civil enforcement cases are currently being conducted by outside counsel to legitimate pharmaceutical manufacturers who have developed a Lanham Act Enforcement practice expertise.