



Trademark Law Used to Block Foreign Gray-Market Pharmaceuticals – Is This the Wave of the Future?

In August, the U.S. Court of Appeals for the Fourth Circuit affirmed in [*Gilead Sciences, Inc. v. Meritain Health, Inc.*](#) a preliminary injunction (PI) barring a group of importers, a third-party administrator, and a pharmacy benefit manager (PBM) from importing or facilitating the importation of foreign gray-market Gilead Sciences Inc. medications into the U.S. This is the latest appellate decision addressing the use of federal trademark law to stop the importation of gray-market pharmaceuticals.

What Is the Gray Market?

Gray market goods are “genuine products bearing a valid U.S. trademark that are imported without the U.S. trademark holder’s consent.”¹ Sections 32 and 42 of the Lanham Act reach such goods when they are “materially different” from the goods authorized for domestic sale, because those differences risk consumer confusion and erode goodwill.² Gilead addressed the material differences that supported enforcement against the unauthorized sale of otherwise genuine imported pharmaceuticals, including foreign-language labeling, the absence of U.S.-specific drug-interaction and storage warnings, a boxed hepatitis B warning, and a National Drug Code.

Background: The Dispute

The dispute began after a Maryland patient received a Turkish version of Gilead’s HIV medication BIKTARVY (emtricitabine and tenofovir alafenamide tablets), used to treat HIV-1 infection in adults and children, in the mail. This version was an authentic Gilead product packaged for sale only in Turkey and was never approved by the U.S. Food and Drug Administration for U.S. distribution. The patient’s employer used a

third-party administrator (TPA) to administer a self-funded health plan that used an “alternative funding program” to source medications abroad, routing the order through several intermediaries to a Turkish pharmacy. Gilead sued under the Lanham Act, and the district court entered a PI.

The Court’s Analysis: Were the Drugs “Genuine”?

The central question was whether the imported drugs were “genuine” under the Lanham Act. Goods bearing authentic marks are not considered genuine, the court explained, if they materially differ from authorized domestic goods or fall outside the owner’s quality-control system. Specifically, the court found the Turkish BIKTARVY materially different because it was labeled in Turkish and omitted the “Rx only” symbol, the National Drug Code number, drug-interaction and child-safety warnings, and storage instructions found on the domestic product. Chemical identity made no difference because material differences are not limited to physical composition. The drugs also bypassed Gilead’s temperature-monitored shipping, traceability measures, recall procedures, and closed distributor network, thereby failing the quality-control test as well. Because the goods were not genuine, the first-sale doctrine did not bar the claims.

Contributory Liability and Remedy

The court also held the intermediaries, Meritain Health and ProAct, contributorily liable. A defendant is liable for continuing to supply services to a party it knows or has reason to know is infringing, without any requirement of prior notice from the trademark holder. Finally, the court applied the Trademark Modernization Act’s rebuttable presumption of irreparable harm and rejected the argument that consumer cost savings outweighed the equities, because that argument assumed the imports were genuine. The injunction was affirmed in full.

Why It Matters

For brand owners, the decision confirms an important principle: a product can infringe a manufacturer’s trademark even when the manufacturer made the product and it is chemically identical to the U.S. version. What matters is whether the imported product conforms to what U.S. consumers expect. Where the labeling

differs, required disclosures are absent, or the product has moved outside the owner's quality-control system, it will not be treated as "genuine," and any one of those deficiencies is sufficient to support a claim. Additionally, intermediaries such as PBMs and claims processors face real exposure for facilitating importation schemes. Companies that operate or support alternative funding programs for their health plans should reassess their sourcing, and manufacturers should document the differences between their domestic and foreign products, maintain provable quality controls, and record their marks with customs. We will continue to monitor issues arising from this case, as it has implications for health plans, PBMs, and pharmaceutical product track-and-trace systems, which are integral to our life sciences services and representations.

This blog was drafted by [Brian Malkin](#), co-lead of the Spencer Fane FDA Pharmaceutical and Biologics Market Team, [Daniel Hwang](#), lead of the EU Intellectual Property Market Team, and [Crystal Armstrong](#), a member of the Trademark Portfolio Market Team. For more information, visit spencerfane.com.

¹ [K Mart Corp. v. Cartier, Inc.](#) (S. Ct. 1988)

² [Martin's Herend Imports, Inc. v. Diamond & Gem Trading USA, Co.](#) (5th Cir. 1977)

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