Patents

Impression Products and the U.S. Branded-Drug Market

By Eric H. Weisblatt

Because U.S. patent portfolios are useless to prevent importation of drugs that were made in the United States and exported, branded U.S. drug companies could face a tidal wave of reimported drugs they sold abroad. The large worldwide branded-drug price differentials and the strength of the dollar will lead enterprising entrepreneurs to intensely study a business model that purchases brand-name drugs abroad for importation into the United States. In response, the drug companies might have to move production overseas or sue their customers. Today, neither option seems appealing.

On May 30, the United States Supreme Court decided that once a patented article was sold anywhere in the world, the patentee exhausts its patent-derived right to control the article. Impression Prods., Inc. v. Lexmark Int'l Inc., U.S., 122 USPQ2d 1605 (2017).

In that case, Lexmark sued for infringement of its printer cartridges that were sold by Lexmark in the United States and abroad. Lexmark asserted that contractual obligations prevented the U.S.-sold cartridges from being re-manufactured and resold and that no one had the authority to import cartridges sold outside the United States. Id. at 1609. Impression countered that Lexmark’s sales in the United States and abroad exhausted Lexmark’s patent rights and that no contractual obligation could resurrect them. Id.

The Supreme Court first found that Lexmark might have recourse against its customers for violating the contractual restrictions connected to their purchase of the cartridges, but those restrictions “do not entitle Lexmark to retain patent rights in an item that it has elected to sell.” Id. at 1610. That is of little solace to Lexmark given the cardinal rule that one does not sue customer/consumers.

For the cartridges sold abroad, Lexmark argued that a foreign sale did not trigger patent exhaustion because Lexmark never transferred its U.S. patent rights to foreign purchasers. Id. at 1613. The Supreme Court rejected any notion that territoriality concerns had any relevance to patent exhaustion: “[R]estrictions and locations are irrelevant; what matters is the patentee’s decision to make a sale.” Id. at 1615.

This situation has arisen with other elements of intellectual property. In the 1980s the strength of the dollar led individuals to purchase in Europe unpatented luxury goods at a discount. These goods could be imported into the U.S. and resold at a profit in direct competition to the commerce streams created and protected by the manufacturers of the luxury goods. Faced with discount competition at outlets believed to be inferior to the official outlets, many manufacturers of luxury goods tried to use their trademark rights and copyrights to prevent discounting.

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Branded drug manufacturers face similar concerns. The huge difference in the prices of branded drugs throughout the world is well-studied and documented. See, for example, https://www.bloomberg.com/graphics/2015-drug-prices/. The Division of Import Operations and Policy of the FDA has taken the position that, “The United States Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. section 331) prohibits the interstate shipment (which includes importation) of unapproved new drugs. Thus, the importation of drugs that lack FDA approval, whether for personal use or otherwise, violates the Act. Unapproved new drugs are any drugs, including foreign-made versions of U.S. approved drugs, that have not been manufactured in accordance with and pursuant to an FDA approval.” (Emphasis supplied.)

So, albeit with the issues of compliance with FDA packaging and labeling rules aside, one might find that branded drugs made in the United States and shipped overseas are outside the scope of the FDA’s prohibition. A survey of the prescription drugs that qualify for this exception has not been accomplished. However, it is a certainty, given the potential profits, that people and companies involved in the distribution of branded drugs are examining the situation and looking for opportunities, not to mention that state and local governmental entities are desperately searching for ways to decrease their spending on health care. Whether contractual obligations imposed by the branded drug companies on their foreign distributors are able to successfully prevent a “grey market” in authentic branded drugs made in the United States but exported to overseas markets involves serious foreign law questions of restraint on alienation and attempts to monopolize. The transfer of drug manufacture abroad has both policy and cost considerations. And, finally, although the latest effort involved an individual’s right to import prescription drugs from Canada (see the proposed “The Safe and Affordable Drugs from Canada Act” explained at https://www.klobuchar.senate.gov/public/2017/1/senators-klobuchar-and-mccain-introduce-the-safe-affordable-drugs-from-canada-act), congressional action on the ability to import authentic branded drugs into the United States cannot be discounted because of the perceived high price paid for those drugs in the United States.

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