Pharmacists Should Keep A Close Eye on Skinny Label Litigation

The rise of the generic industry can be attributed to the Hatch Waxman Act. *"The Drug Price Competition and Patent Term Restoration Act, better known as the Hatch-Waxman Act, is a comprehensive legal framework enacted by Congress in 1984 to streamline the process for generic pharmaceutical approvals and preserve incentives for innovation, including the creation of a procedure for patent litigation involving generic pharmaceuticals. The Hatch-Waxman Act established the legal and economic foundation for today's generic pharmaceutical industry."*[1]

The whole reason this law is beneficial is to ensure that patients have access to medications through marketplace competition. Hatch-Waxman does allow generic companies to go to market faster. This happens when generic companies are allowed to "carve out" from their labels any specific uses that have been approved by the FDA for the innovator's products. Thus a generic can come to the market on one indication for example when an innovator's drug has been approved for multiple indications.

This "skinny label" allows for FDA approved generics to come to market prior to when brand name patents have expired in order to create a more competitive marketplace. Brand companies (innovators) look disfavorably upon this practice because it weakens their attempts at market exclusivity through methods such as patent-thickening, evergreening or even the method of using orphan drug classifications to protect against generic competition. Unfortunately for the generic industry, brand pharmaceutical interests have been slowly chipping away at skinny labeling.

The ruling in GlaxoSmithKline LLC v. Teva Pharm. USA, Inc. has resulted in an important development. "*On August 5, 2021, the U.S. Court of Appeals for the Federal Circuit ruled that substantial evidence supported the conclusion that Teva induced infringement of GSK's patent even during the time period when Teva used a "skinny label," or Section viii carve-out, that omitted the heart failure indication. The Federal Circuit found Teva's conduct in marketing and advertising the generic drug sufficient to establish inducement despite the skinny label. Although this decision is unlikely to impact the analysis of "skinny labels" in a pre-marketing context, once a generic drug is launched, innovator companies should pay attention to how the generic advertises and markets the product, as this evidence—including any statements regarding therapeutic equivalency to the innovator product—may be sufficient to establish induced infringement even with a Section viii carve-out."*[2]

While this seems like an issue that will not harm pharmacy, the issue is worth monitoring closely. While I foresee more litigation between brand and generic manufacturers over this issue, one has to start to wonder whether pharmacists and others such as pharmacy benefit

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[1] What is Hatch -Waxman? https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/Fact-Sheet_What-is-Hatch-Waxman_June-2018.pdf

[2] Federal Circuit Vacates Judgment, reinstates Jury's Verdict of Induced Infringement, September 2021 Commentaries Jones Day https://www.jonesday.com/en/insights/2021/09/federal-circuit-vacates-judgment-reinstates-jurys-verdict-of-induced-infringement

managers (PBMs) will be brought into this argument since the pharmacist is often making generic substitutions at the counter while PBMs are in favor of utilizing generics on their formularies. Until we get additional clarity from either the courts or Congress, it is likely status quo for pharmacies.

NPSC will be in touch with the National Community Pharmacists Association (NCPA) and other interested stakeholders as this issue continues to develop.

For additional information on this issue contact Ron Lanton at 240-482-6060 or email him at rlanton@lantonlaw.com.