

## What Form Is It? Lessons From 13 Polymorph Pharmaceutical Cases

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Partner Brian Sodikoff, associate Martin Masar and intern Cole Garrett discuss the risks and rewards for both generic and brand firms in this article on the current landscape of polymorph patent litigation. Under FDA regulations, different polymorphs of an active substance are considered the "same" drug under Hatch-Waxman. However, pharmaceutical companies often patent the different polymorphs of a drug, which can result in litigation before the FDA approves generic versions of the drug. Generic manufacturers have the option of trying to design around polymorph patents, in addition to pursuing a traditional invalidity challenge. In the article, the authors review more than a dozen cases surrounding polymorphs that show that this area is complex, fact-specific and full of potential landmines for generic and brand pharmaceutical companies alike. A detailed scientific analysis and consideration of numerous, and at times conflicting, legal precedent are required to determine the risks of infringement and validity of polymorph patents.

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