

There Is No Specific Intent to Induce Infringement Where a Statement of the Infringing Use in the Drug Product Label Is Permissive, Rather Than Mandatory

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HZNP Medicines LLC, Horizon Pharma USA, Inc. v. Actavis Laboratories UT, Inc., Nos. 2017-2149, 2017-2152, 2017-2153, 2017-2202, 2017-2203, and 2017-2206 (Fed. Cir. Oct. 10, 2019)

The patent owner in an Abbreviated New Drug Application (ANDA) infringement case appealed the district court's summary judgment of no induced infringement. The patent owner alleged that the warning in the alleged infringer's label would induce infringement of its method-of-use patents. Notably, the relevant claims recite a three-step method for treating osteoarthritis: (1) applying the topical drug to the knee; (2) waiting for the drug to dry; and (3) applying another topical product to the knee, such as sunscreen or insect repellent, after the drug had dried. The alleged infringer's label instructed users to apply the drug to the knee and then "wait until the treated area is dry before applying sunscreen, insect repellent, lotion, moisturizer, cosmetics, or other topical medication." Despite the label expressly reciting the infringing use, the district court found that because the label simply permits, rather than requires, the subsequent topical application, there was no specific intent to induce infringement.

The Federal Circuit affirmed, finding that while the accused infringer's label establishes that some users might infringe, it does not establish that the label instructs users to perform the patented method. Further, because the proposed label went beyond the patent owner's claims by warning against clothing, cosmetics, and lotion, the label does not encourage infringement.

Judge Newman dissented in part, stating that the fact that patients may not always comply with instructions "does not insulate the provider from infringement liability" where the product label "instructs users to perform the patented method."

[A copy of the opinion can be found here.](#)

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