Patenting the Product Label

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When the U.S. Food and Drug Administration approves a new drug, it also approves a package insert of the drug, known as a "product label." A pharmaceutical company marketing a generic product is required to package their product with a product label. The generic product label is typically substantially similar to the brand product label. Rarely does a generic company perform a step recited in a method of use patent, such as "treating a patient." Therefore, to establish patent infringement, a patentee must demonstrate the company induced a third party, *e.g.* the doctor or patient, to perform the claimed method.

Overview of Inducement as Applied in the Pharmaceutical Context

- A party "causes, urges, encourages, or aids" a direct infringement by another party.
- Must establish that the alleged infringer knowingly induced infringement and had specific intent to encourage the third party to infringe the patent.
- Pharmaceutical company has no intent to induce infringing use if the product label does not instruct a third party to use the product in an infringing manner.

What Constitutes an "Instruction for Use" in an Infringing Manner in the Product Label?

- It is not sufficient that the product label describes an infringing mode. The label must "recommend," "encourage," or "promote" the infringing use.
- Vague label language cannot be combined with speculation about how physicians may act.

Prosecution Strategies Regarding the Product Label?

- If possible, draft claims with the exact language included in the "Indications and Usage" and/or "Dosage and Administration" sections of the product label.
- Draft claims to match "warnings" included in the product label.
- File applications directed to new indications and patient subpopulations, especially if there is a difference in efficacy in a particular patient subpopulation.
- File applications to combination therapies, especially if the combination impacts the safety and efficacy of the original patient population.
- File applications with claims directed to the pharmacokinetic parameters *e.g.,* C_{max}, T_{max}, and AUC, included on the product label.
- If must prosecute mechanism of action claims, try to tie the mechanism of action to the approved indication.
- Draft claims with divided infringement defense in mind. All steps must be performed by a single party or under the direction of that party.