TAKEDA PHARMACEUTICALS U.S.A. v. WEST-WARD PHARMACEUTICAL CORP., Appeal Nos. 2015-1139, 2015-1142 (Fed. Cir. May 6, 2015). Before Newman, Dyk and Hughes. Appealed from D. Del. (Judge Robinson).

Background:

Plaintiff owns patents relating to methods of administering a drug to treat gout. In 2009, plaintiff was the first drug manufacturer to receive approval from the FDA to market the drug for treatment of gout flares. Plaintiff conceded that administering the drug for prophylaxis of gout flares is not covered by the asserted patents. In 2010, defendant sought FDA approval of a product for prophylaxis of gout flares and submitted a "paper NDA" under § 505(b)(2) of the Hatch-Waxman Act. In September of 2014 the FDA granted defendant approval to market its product for prophylaxis of gout flares. Defendant launched its product, and plaintiff filed suit asserting induced infringement based on defendant's labeling of its product (defendant's label stated that its product is "indicated for prophylaxis" and that the "safety and effectiveness of [it] for acute treatment of gout flares during prophylaxis has not been studied;" the label also said that "[i]f you have a gout flare while taking [the product], tell your healthcare provider").

The district court granted plaintiff's request for a temporary restraining order on October 9, 2014, restraining defendant from selling its product. On November 4, 2014, the district court denied plaintiff's motion for preliminary injunction on the ground that plaintiff did not meet its burden of showing a likelihood of success on the merits for its induced infringement claims. The district court concluded that, although defendant failed to raise a substantial question regarding the validity of the patents, plaintiff had not met its burden of showing likelihood of proving induced infringement. Plaintiff appealed the denial of preliminary injunction.

Issue/Holding:

Did the district court err in denying plaintiff's motion for preliminary injunction? No, affirmed.

Discussion:

The Federal Circuit determined that the vague label language at issue cannot be combined with speculation about how physicians may act to find inducement. Additionally, plaintiff conceded that mere knowledge of off-label infringing uses of defendant's product would not establish inducement. Furthermore, at least because a host of alternatives for treating gout flares were available, the Federal Circuit determined that there was insufficient evidence that the label would necessarily lead doctors who are consulted by patients taking defendant's product to prescribe an off-label infringing use of the product (i.e., to treat acute gout flares).

Accordingly, at least because the label failed to encourage, recommend, or promote infringement, the Federal Circuit concluded that the district court did not abuse its discretion in denying a preliminary injunction on the ground that plaintiff had failed to meet its burden to show a likelihood of success on the merits.