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Federal Circuit: Reverses Motion to Dismiss—Generic Manufacturer's Label Combined with its Expansive Public Statements Plausibly Induced Infringement

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The Federal Circuit reversed a decision from the District of Delaware dismissing a case for failing to plead induced infringement because the totality of the evidence raised fact questions that could not be resolved on a motion to dismiss. The Federal Circuit expressed doubts about whether appellee's FDA-approved label alone, which carved out the claimed indication, was sufficient to actively induce. But the court held appellee's label combined with its public statements that broadly refer to its drug as a generic version and provide usage and sales data for carved out indications, created a plausible basis for pleading induced infringement.

This appeal stems from an infringement suit brought in the District of Delaware for infringement of claims for reducing cardiovascular events brought against a generic manufacturer of appellant's drug, Vascepa. In 2012, Vascepa was approved for the treatment of severe hypertriglyceridemia (SH). When Vascepa was first approved, its label included an express "limitation of use," stating its effect on cardiovascular mortality and morbidity was not yet determined. In 2019, the FDA approved Vascepa to reduce cardiovascular risk. As a result of this approval, the limitation of use was removed from the Vascepa label.

Appellee in this case sought a label for the SH indication, and initially included the limitation of use language in its label. After Vascepa was approved to reduce cardiovascular risk, appellee revised its ANDA to indicate that it was seeking a "skinny label" for only the SH indication and would carve out the cardiovascular risk indication. Appellee also removed the limitation of use language from its proposed label. Around the time appellee received

approval for its generic Vascepa, it issued several press releases touting its drug as generic Vascepa without limitation and citing to overall U.S. sales of Vascepa, including sales attributable to the cardiovascular risk indication. Appellee also established a website that included, in small letters, the statement that its generic was approved for fewer than all approved indications for Vascepa.

The district court dismissed appellants complaint for infringement for failing to adequately plead inducement, and more specifically for failing to adequately allege acts that constitute active inducement of the asserted patents. According to the district court, the warnings of side effects in appellee's label did not recommend, encourage or promote infringement. Likewise, the press releases, while potentially evidence of intent, did not plausibly evidence an inducing ***act***.

On appeal, the Federal Circuit disagreed. The Federal Circuit took issue with the district court's evaluation of the allegations, holding that on a motion to dismiss where the generic product is already approved (i.e., not your typical Hatch-Waxman case), the evidence must be viewed in its totality, not piecemeal as the district court had done. The Federal Circuit explained that this was not a typical "skinny label" case where the allegations are based solely on the label. Instead, the evidence here encompassed the ***combination*** of the label, public statements, and marketing materials, including public statements that provide usage information and sales data about the cardiovascular risk indication. Here, the appellee did not merely market its drug as a generic or merely skinny label around an indication, it did much more. Thus, based on the totality of the material cited in the complaint, the Federal Circuit held it is plausible that a physician could discern an encouragement to use the generic Vascepa for indications other than SH.

Amarin Pharma, Inc. v. Hikma Pharms. USA Inc., Case No. 2023-1169 (Fed. Cir. Jun. 25, 2023)

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