AMARIN PHARMA, INC. v. HIKMA PHARMACEUTICALS USA INC., Appeal No. 2023-1169 (Fed. Cir. June 25, 2024). Before Moore, Lourie, and Albright. Appealed from D. Del. (Judge Andrews).

Background:

Amarin, a brand drug manufacturer, initially marketed the product VASCEPA® to treat Severe Hypertriglyceridemia (SH indication) and later obtained FDA approval for a second use to reduce Cardiovascular risk (CV indication). Hikma, a generic manufacturer, filed an ANDA for a generic VASCEPA® to treat SH indication. When Amarin's CV indication was approved, Hikma adopted a "skinny label" approach, which did not include the CV indication (section viii carve-out), though Hikma's press releases, website, and marketing materials all described Hikma's product as the generic version of VASCEPA®.

Amarin sued Hikma for induced infringement of patent claims directed to the CV indication. Hikma filed a motion to dismiss for failure to state a claim. The District Court referred the case to a magistrate judge, who recommended denying Hikma's motion. The magistrate judge concluded that, based on the totality of the allegations, which relied not only on the content of the skinny label but also on Hikma's press releases and website, Amarin had "pleaded an inducement claim . . . that is at least plausible." On *de novo* review, the District Court separated Amarin's allegations into two categories—Hikma's label and Hikma's public statements—addressing each separately.

The District Court concluded as a matter of law that although Amarin was right that Hikma's label's silence regarding CV risk reduction communicates to the public that icosapent ethyl could be used to reduce CV risk, 'merely describing an infringing mode is not the same as recommending, encouraging, or promoting an infringing use.' Because it found that Amarin's complaint failed to plead inducement based on either Hikma's label or public statements, the District Court granted Hikma's motion to dismiss. Amarin appealed.

Issue/Holding:

Did the District Court err in granting Hikma's motion to dismiss for failure to state a claim under the law of the regional circuit? Yes, reversed.

Discussion:

The Federal Circuit found that the allegations of the complaint transform this case from a pre-approval, label only induced infringement claim to one where the alleged infringement is based on the generic manufacturer's (Hikma's) skinny label *as well as* its public statements and marketing of its already-approved generic product. In such a scenario, the Federal Circuit reviews the allegations of inducement as a whole, not piecemeal. Accordingly, it must consider whether the *totality* of the allegations, taken as true, plausibly plead that Hikma induced infringement.

The Federal Circuit also found that it is undisputed that the "Indications & Usage" section of Hikma's label does not provide an implied or express instruction to prescribe the drug for the CV indication. However, Hikma's press releases broadly refer to the product as a "generic version" of VASCEPA® and provide usage information and sales data for the brand-name drug from which it is plausible that a physician could discern an encouragement to use the generic for purposes beyond the approved SH indication. Thus, despite its section viii carve-out, Amarin has plausibly pleaded that Hikma induced infringement of Amarin's asserted patents.