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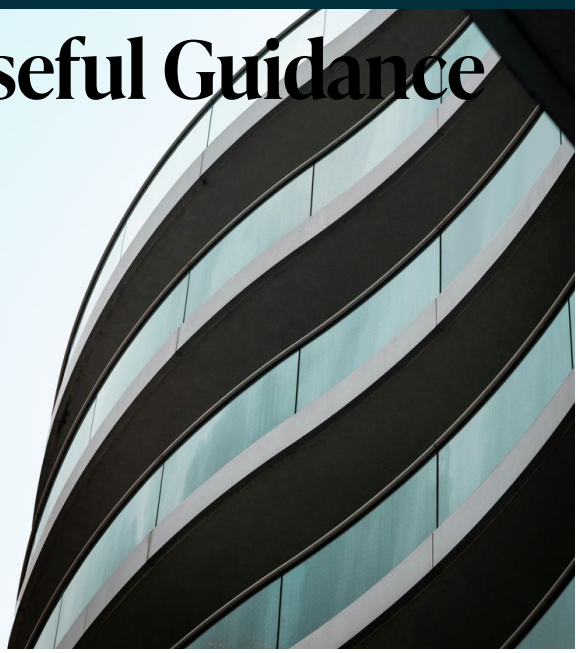
Federal Circuit Provides Useful Guidance on Skinny Label Claims



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When the Federal Circuit resurrected Amarin's "skinny label" infringement claims against Hikma last month, it offered some important lessons for drug developers. The precedential decision helps clarify the kinds of promotional statements by a follow-on manufacturer that can be used to sufficiently plead induced infringement. Going against the recommendation of the magistrate judge, the Delaware District Court summarily dismissed Amarin's claims that Hikma's skinny-label icosapent ethyl product infringed patents covering a use of Vascepa.

The Federal Circuit tacitly acknowledged that Hikma's skinny label may not encourage an infringing use as a matter of law. However, the court noted that Amarin's inducement theory relied on the label *in combination* with public statements and marketing materials. So, what kinds of public statements proved problematic for Hikma? First, the court pointed to the use of the therapeutic category of "Hypertriglyceridemia," which allegedly encompasses both infringing and noninfringing uses. Second, the court noted that Hikma referred to its product as generic of Vascepa. The court suggested that Hikma should have said its product is "AB-rated" to Vascepa instead, meaning it is therapeutically equivalent for the *labeled* conditions of use. Third, Hikma touted sales figures for Vascepa that it knew were largely attributable to the off-label use of its product. The Federal Circuit found that these statements could be taken together with certain wording on the label to plausibly state a claim for induced infringement. Summary dismissal was thus inappropriate without further development of the factual record.

Of course, this reversal of the Delaware District Court infuses even more uncertainty into the already turbulent space of skinny-labeling case law. But this decision does provide some actionable guidance to drug developers that may seek to show or avoid induced infringement. First, any cited sales figures for the brand product should not include off-label uses. Second, follow-on drug developers should consistently refer to any products with a skinny label as "AB-rated" (or equivalent) rather than "generic." Of course, this last point depends on the label itself not encouraging an infringing use (*i.e.*, being "skinny enough"). By paying close attention to this developing area of the law, generic drug companies can put themselves in the best position to quickly dispose of any claims for induced infringement involving products with section viii statements and skinny labels.

Clarity and consistency in a generic manufacturer's communications regarding a drug marketed under a skinny label may be essential in avoiding liability for induced infringement.

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