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Skinny Labels May Not Be Dead: Delaware District Court Distinguishes GSK, Dismisses Induced Infringement Claim

Proskauer in Life Sciences on **January 26, 2022**

In one of the first district court opinions applying the Federal Circuit's recent *GSK* decision on induced infringement in the context of label carve-outs (the "*GSK* decision," discussed here and here), Judge Richard Andrews in the District of Delaware held that plaintiff Amarin Pharma ("Amarin") failed to plead facts sufficient to show that Hikma Pharmaceuticals' ("Hikma") carved-out product label and/or public marketing statements induced infringement of Amarin's patents. The holding suggests that carved-out labels (so-called "skinny labels), despite the *GSK* decision, continue to provide some measure of protection from liability based on induced infringement.

The GSK Decision

To briefly recap, in August 2021, the Court of Appeals for the Federal Circuit released the *GSK* decision—its latest authoritative opinion on induced infringement in the context of label carve-outs. The majority affirmed a jury verdict of induced infringement against Teva, finding that, although the label omitted any explicit reference to the patented indication, expert testimony tied other language in Teva's label to the patented use. The Court also found that two Teva press releases supported the jury's verdict of induced infringement. The first press release advertised Teva's drug as "indicated for treatment of heart failure" without differentiating between congestive heart failure (the patented indication) or post-MI LVD (an unpatented indication). The second press release's stated that Teva received approval to market "its Generic version of GlaxoSmithKline's cardiovascular agent Coreg"—and expert testimony further established that the phrase "cardiovascular agent" indicated to doctors they could use Teva's carvedilol for all indications, including heart failure.

The August 2021 *GSK* decision emphasized that merely noting that a product is "AB rated" or "therapeutically equivalent" to a brand-name drug does not, on its own, support a finding of induced infringement. However, such statements, when coupled with a label that does not effectively carve-out a patented use, can support a finding of inducement.

Amarin's Allegations of Inducement

Amarin sells Vascepa (icosapent ethyl), which is approved for: (1) the treatment of severe hypertriglyceridemia, which is an unpatented use; and (2) cardiovascular risk reduction, which is a patented use. In November 2020, Hikma received FDA approval to sell a generic version of Vascepa with the patented cardiovascular risk reduction indication omitted from the label, leaving only the unpatented severe hypertriglyceridemia indication. Amarin sued for infringement, alleging that Hikma's label is "not skinny enough" and that, together with Hikma's public statements, induces infringement of the patents covering the cardiovascular risk reduction indication. *Amarin Order*, slip op. at 4.

Amarin contended that, despite omitting cardiovascular risk reduction from the Indications and Usage section, Hikma's label nevertheless teaches cardiovascular risk reduction for two reasons. First, Hikma's label contains a warning regarding side effects for patients with cardiovascular disease ("Icosapent ethyl may cause serious side effects, including: . . . Heart rhythm problems which can be serious and cause hospitalization in people have happened in people who take icosapent ethyl, especially in people who have heart disease or diabetes with a risk factor for heart disease"). Amarin argued that the warning's reference to "a risk factor for heart disease" signals to physicians that Hikma's drug may be prescribed for the patented cardiovascular risk reduction indication. *Id.* at 6.

Second, Amarin argued, Hikma's label teaches cardiovascular risk reduction because it does not state that the drug should *not* be used for cardiovascular risk reduction. Specifically, Amarin pointed out that Hikma removed language that "the effect of icosapent ethyl on cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined" (the "cardiovascular limitation language"). According to Amarin, because other drugs in the same class have not been shown to reduce cardiovascular risk, the omission of the cardiovascular limitation language amounts to an "affirmative statement" that would be "understood in the field to teach that Hikma's product *has* been proven to reduce cardiovascular risk and to encourage its use for that purpose." *Id.* at 6-7.

Amarin also alleged that Hikma induced infringement via public statements, including its Hikma's press releases citing the total sales figures of Vascepa, which include sales for the patented indication. Hikma's press releases further state that its product is the "generic equivalent to Vascepa" and that "Vascepa is a prescription medicine that is indicated, in part, as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia." Hikma's website touts that Hikma's product is "AB rated" in the "Therapeutic Category: Hypertriglyceridemia." According to Amarin, "hypertriglyceridemia," when undifferentiated, includes infringing uses, and therefore Hikma's website (and other public statements regarding equivalence to Vascepa) would induce physicians to prescribe Hikma's drug in an infringing manner. *Id.* at 7-8.

Hikma's Motion to Dismiss

Hikma moved to dismiss, arguing that Amarin failed to plead sufficient facts alleging Hikma's inducement to administer icosapent ethyl to reduce cardiovascular risk. Judge Andrews referred the matter to Magistrate Judge Jennifer Hall, who issued a Report and Recommendation to deny Hikma's motion. According to Judge Hall, Amarin's factual allegations, viewed in the light most favorable to Amarin, "plausibly suggest . . . that Hikma's label and public statements could instruct and/or encourage third parties to use its product for the cardiovascular risk reduction indication." *Amarin v. Hikma*. Two days after Judge Hall issued her Report and Recommendation, the Federal Circuit issued its August 2021 *GSK* decision.

Judge Andrews heard oral argument in October 2021 and, on January 4 2022, issued an opinion granting Hikma's motion to dismiss, over Judge Hall's Report and Recommendation. In granting Hikma's motion, Judge Andrews distinguished Hikma's label and advertising statements from those at issue in the *GSK* decision.

First, Judge Andrews held that the statement regarding cardiovascular side effects "is hardly instruction or encouragement" and is instead merely a warning. Second, Judge Andrews found no support for Amarin's argument that the removal of the cardiovascular limitation language teaches that the drug may be prescribed for cardiovascular risk reduction, and noted that the Federal Circuit has previously rejected the argument that generic labels must discourage use of the patented indication. Judge Andrews further stated that even if Amarin could show that the silence of Hikma's label regarding cardiovascular risk reduction communicates that icosapent ethyl can be used to reduce cardiovascular risk, "merely describing an infringing mode is not the same as recommending, encouraging, or promoting an infringing use." Thus, Judge Andrews found that Amarin pled no facts sufficient to show that Hikma's carved-out label would lead a physician to prescribe the drug for the patented use. *Amarin Order*, slip op. at 6-7.

Judge Andrews went on to consider whether Amarin pled sufficient facts to show that Hikma's public statements induced infringement—in particular, Hikma's statement that its product is "AB rated" in the "Therapeutic Category: Hypertriglyceridemia." Crediting Amarin's assertion that the category "hypertriglyceridemia" includes infringing uses, the court framed the issue as "whether this is enough, without a label or other public statements instructing as to infringing use, to induce infringement." *Id.* at 7-8.

With respect to Hikma's touting of "AB rating," Judge Andrews noted that the *GSK* majority expressly declined to hold that an AB rating in the context of a "true" carve-out (in which the label had no infringing indications) would be evidence of inducement. Because Hikma's was a "true" skinny label, Judge Andrews found that its statement of AB equivalence was not evidence of inducement. Judge Andrews also noted that, although Hikma's citation of Vascepa's sales figures may show evidence of Hikma's intent to induce infringement, "[i]ntent alone is not enough; Amarin must plead an infringing act." According to Judge Andrews, Amarin failed to sufficiently plead an act that could "rise to the level of encouraging, recommending, or promoting taking Hikma's drug for the reduction of cardiovascular risk." *Id.* at 8-9.

Judge Andrews found that unlike Teva's press releases in *GSK*, Hikma did not point to Vascepa's patented uses in describing its product as a "generic equivalent." *Id.* at 9. Although it is not clear from the opinion, Judge Andrews may have been referring to Hikma's statement that its product is a "generic equivalent to Vascepa" and that "Vascepa is a prescription medicine that is indicated, *in part*, as an adjunct to diet *to reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia*" (emphasis added)—because this statement of equivalence refers specifically to the non-patented indication and is silent on the patented indication. In *GSK* , by contrast, Teva's statement of equivalence was coupled with a statement referring to treating undifferentiated "heart disease" (which includes the patented indication), and there was no apparent effort to parse out the non-patented indication in public statements.

Takeaways

Judge Andrews' opinion confirms the vitality of the skinny label defense to alleged induced infringement. Relatedly, the decision potentially provides a roadmap for the types of advertising statements that side-step liability (*e.g.*, statements of equivalence that mention non-infringing uses but are silent as to infringing uses), compared to those that risk liability for induced infringement (*e.g.*, statements of equivalence that fail to adequately distinguish between infringing and non-infringing uses). It is also potentially noteworthy that, although Judge Andrews ruled for Hikma, he found that Hikma's citation of Vascepa's total sales figures showed intent to induce infringement.

The procedural posture of this case versus the *GSK* case is also worth noting. The review in the *GSK* case was of a judgment as a matter of law ("JMOL") reversing a jury verdict of induced infringement. The majority noted that, although there was sufficient evidence to support the jury verdict (and thus insufficient basis for a JMOL), there was also ample evidence that would have supported the opposite verdict. Despite some facial similarity between Amarin's allegations and the facts in *GSK*, Amarin's complaint did not survive a motion to dismiss. If it did, Amarin would have had the opportunity to bolster its case with expert testimony and other evidence, and potentially receive a favorable ruling, as GSK did. Instead, Hikma was able to prevail at an early stage and (for now) prevent further development of the record. This highlights the importance of early case dispositive motions and the need for litigants to consider early development of expert testimony regarding the impact of the generic product label, and public statements by generic manufacturers, on inducement (or lack thereof).

This is not likely the end of the induced infringement saga in general, nor even in this case If Amarin appeals the district court's decision, it will be interesting to follow how the Federal Circuit views Amarin's claims in light of the Court's recent decisions in this area. Additionally, although not discussed here, the district court separately allowed Amarin to proceed against co-defendant Health Net (a health insurance company) on a novel induced infringement theory that Health Net's formulary and authorization process are implemented in a way that encourages physicians to use the generic product for the patented indication. It will be interesting to see how this novel induced infringement theory ultimately fairs. Finally, the *GSK* case itself is on remand, with unresolved questions (for example, the issue of "equitable estoppel"—that Teva detrimentally relied on GSK's statements in crafting its partial label), and future holdings in that case may yet impact the law of induced infringement.

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