Axinn IP Update: Supreme Court Denies Cert. in Skinny Label Case, but the Impacts from GSK v. Teva Continue

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Today, the Supreme Court denied certiorari in *Teva Pharms. USA, Inc. v. GlaxoSmithKline, LLC*, 22-37, locking in the Federal Circuit's second panel decision (hereafter "*GSK v. Teva*"), which held that Teva's attempted section viii carveout of an indication covered by a patented method of use was not "skinny" enough to avoid being liable for infringement.

Although the Court did not state why *certiorari* was denied – as is common – the Order List stated that Justice Kavanaugh would grant the petitions for *certiorari*. One possible reason that the Court believes that *certiorari* is not ripe is that Teva's affirmative defense of equitable estoppel, i.e., if GSK's representations to FDA were at odds with its enforcement efforts in this case, still needs to be considered on remand.

GSK in its supplemental brief to the Supreme Court has already indicated what its argument will likely be on the equitable estoppel issue on remand. Specifically, GSK argued that the parties are confusing the history of FDA's requirements and that FDA did not impose the obligation to identify sections of the labeling describing claimed methods of use until 2016, almost a decade after the events in question. And even if FDA had required GSK to identify these sections, FDA and Teva could not have relied on GSK's statements because GSK submitted its Form 3542 six months *after* Teva launched its "skinny label" generic carvedilol. GSK's arguments on remand will likely be similar, namely that there was no "misleading conduct" and therefore no equitable estoppel.

Nevertheless, there are still larger implications from *GSK v. Teva* than the issues on remand. For instance, district courts are grappling with *GSK v. Teva*, including the notable *Amarin v. Hikma* case. In *Amarin*, a partial label was deemed "skinny" enough for the generic company to avoid infringement. However, an induced infringement claim against an insurer (Health Net) survived a motion to dismiss based on the alleged favorable formulary position for the generic drug and a prior authorization form that continued to list the patented indication for the generic capsules.

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Further, FDA has noted its "concern" with *GSK v. Teva* and joined the United States' *amicus* brief, and has also called for legislative amendments to strengthen "skinny labels" and thereby aid in the "timely availability of generic drugs."

Finally, biosimilars are not subject to section viii carveouts, but instead use a similar process for approval for "fewer than all of the reference product's licensed conditions of use." Thus, biosimilar companies should continue to analyze *GSK v. Teva* to assess if they have properly carved out patent-protected conditions of use.

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