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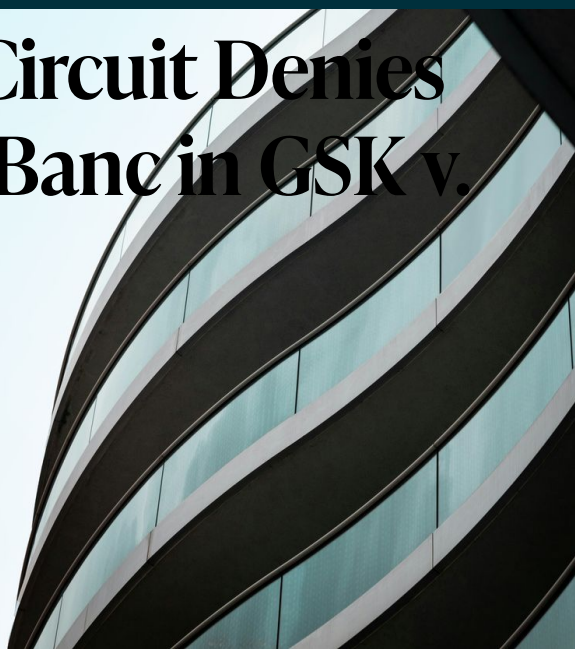
Axinn IP Update: Federal Circuit Denies Petition for Rehearing En Banc in GSK v. Teva



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Last Friday, the Court of Appeals for the Federal Circuit denied the petition for rehearing *en banc* in *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.*, No. 2018-1976 (Fed. Cir. Feb. 11, 2022). With this denial, the Federal Circuit cemented the panel's earlier decision, which reinstated the jury verdict finding Teva liable for induced infringement notwithstanding its use of a Section viii "skinny label" carve-out.

In its two panel decisions, the Federal Circuit held that, despite Teva carving out treatment of congestive heart failure ("CHF") from the label for its generic carvedilol, the jury had sufficient evidence – in the form of press releases and the like – to find that Teva was marketing its drug for the patent-protected CHF indication.

The Federal Circuit's decisions sparked significant concern in the generic pharmaceutical industry as to whether Section viii carve-outs could continue to provide the certainty historically provided to generic manufacturers. Some considered skinny labels a dead letter, while others hoped that the Federal Circuit's decision would be viewed as narrow and fact-dependent, as the Court stressed in its August 2021 revised decision. At a minimum, the decisions increased both business and litigation costs for generic manufacturers, which have had to rethink how they select products for development, market those products, and prepare for any Hatch-Waxman litigations.

With the Federal Circuit's recent denial of rehearing *en banc*, these concerns are now *status quo*. In denying rehearing, the Majority (including the two judges who wrote the initial panel decisions) began by noting that the jury's verdict of inducement was supported by substantial evidence "including the labels, press releases, testimony, marketing materials, and the GSK representations." Maj Op. at 2. The Majority expressed its concern that "GSK's representations to the FDA are at odds with its enforcement efforts in this case," but stated that those concerns fit within the affirmative defense of equitable estoppel rather than within the standard for inducement. Maj. Op. at 5. Judge Prost, renewing her dissent from the initial panel decisions, expressed doubts that an equitable estoppel theory applied, or could apply given the initial panel decision. Prost Dis. at 9-10. If equitable estoppel does apply, in this case (to be decided on remand) or in future cases, it could result "in the exclusion of the label as evidence of inducement," Maj. Op. at 7, and obviate the need for a trial on inducement for the period covered by the estoppel, *id.* at 8 n.3.

In short, Section viii carve-out litigation is here to stay for the foreseeable future. Accordingly, generic developers should coordinate the business units responsible for patent, regulatory, and promotional tasks prior to any drug launch, should seek to understand the risks of all statements prior to and during litigation, and should consider all affirmative defenses, including equitable estoppel. This integrative approach will be key to minimizing any potential inducement claims regarding skinny labels.

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