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GSK v. Teva - No Safe Harbor for Skinny Labels

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Generic pharma and companies interested in new uses for old drugs alike include skinny labels – labels which do not recite uses for the drug that remain covered by a competitor's patent – as part of their intellectual property strategy. However, in *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021), the Federal Circuit provided a stern reminder that a skinny label is not a talisman that wards off liability if the conduct of the accused infringer supports a finding of induced infringement.

What You Need to Know:

- Situations in which some of the patents protecting a pharmaceutical product have expired but the FDA approved use of the drug for the treatment of one or more indications remain covered by the innovator's patents.
- Induced infringement is a theory of patent liability in which a defendant is accused of causing a third party direct infringer to infringe the plaintiff's patent.
- A skinny label is a drug product label that does not include one or more indications for the drug's use but omits others as a strategy to avoid liability for induced infringement.

The case concerns the medicinal product carvedilol. The patent for the drug substance itself expired in 2007. While the FDA originally approved carvedilol for the treatment of hypertension, this indication is no longer under patent protection. However, a later patented indication, congestive heart failure, remained covered by GSK's patents. For a period of several years, Teva marketed a generic version of carvedilol with a skinny label that instructed the use of the product for hypertension but omitted ("carved out") the use that remained covered by GSK's patent.

GSK filed suit, alleging, *inter alia*, that Teva induced infringement of GSK's patent covering the use of carvedilol for the treatment of congestive heart failure, the very use that Teva had carved out of its label. The district court instructed the jury that, "GSK is not required to present hard proof of any direct infringer physician stating, for example, that she read Teva's labels or other Teva materials and that these labels or other Teva materials caused her to prescribe Teva's generic carvedilol in an infringing manner. GSK must prove that Teva's actions led physicians to directly infringe a claim of the '000 patent, but GSK may do so with circumstantial – as opposed to direct – evidence."

Teva argued before the district court that during the period Teva used the skinny label, since it had "carved out" from its label the indication and prescribing information for treatment of congestive heart failure, Teva

could not be found to induce prescribing physicians to infringe GSK's patent directed to the use of the product for the carved out indication. GSK's arguments focused on statements from Teva's press releases as well as other statements and publications by Teva that, in summation and as testified by GSK's expert witness, would lead a doctor to believe that the brand and generic product are therapeutically interchangeable for all uses, including the patented use for the treatment of congestive heart failure. GSK also relied on similarities between the patented and carved out uses to cite portions of Teva's label as itself as inducing infringement.

Ultimately, GSK was successful in convincing a jury that not only did Teva induce infringement of GSK's patent but that Teva did so willfully. This case shows that a skinny label alone is not enough to prevent liability for induced infringement. Rather, if a generic seeks to avoid this kind of liability, their marketing efforts, and in fact all public statements, must be coordinated to avoid anything that could be construed as causing the direct infringer, *i.e.* doctors, to infringe a patent by prescribing the drug for any use still covered by the method patents of a competitor. For example, GSK used Teva's advertising its product has an "AB rating" as well as direct comparisons between the branded product and Teva's product in Teva's catalog to argue that Teva was informing doctors that Teva's product could be prescribed for any use that the branded product could be prescribed. With benefit of hindsight, Teva may wish they had included in these materials some indication that their product was not approved for congestive heart failure to complicate GSK's burden. Making choices that would deny GSK a persuasive story to tell a jury may have avoided the jury verdict that Teva has since been fighting desperately to reverse.

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