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CLIENT ALERT

Carving Out a Patented Indication from a Generic-Pharmaceutical Label Will Not Always Avoid Infringement

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GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc., No. 2018-1976, 2018-2023 (Fed. Cir. Aug. 5, 2021)

The patentee sued the alleged infringer over a generic version of the pharmaceutical drug Coreg® (carvedilol). Coreg® was approved by the FDA for three indications: (i) hypertension, (ii) congestive heart failure ("CHF"), and (iii) post–myocardial infarction left ventricular dysfunction ("post-MI LVD"). From 2007 to 2011, the accused infringer deleted the indication for CHF from its FDA-approved label and included only the indications for hypertension and post-MI LVD. The question was whether the accused infringer's label nevertheless induced infringement of a patent over a method of decreasing mortality caused by congestive heart failure. After a jury verdict of infringement, the district court granted the accused infringer's renewed motion for judgment as a matter of law ("JMOL") of noninfringement, on the basis that the accused infringer's so-called "skinny" label did not cause or encourage the patented use. On appeal, the Federal Circuit vacated the grant of JMOL, reinstated the jury's verdict, and remanded for further proceedings.

The Federal Circuit noted that this was not a case in which the accused infringer was merely marketing and selling its product under a skinny label that omitted all patented indications. Rather, "substantial evidence supports a jury finding that the patented use was on the generic label at all relevant times," and thus the accused infringer "failed to carve out all patented indications." In particular, the court agreed with the patentee that the post-MI-LVD indication on the skinny label encouraged an infringing use—decreasing mortality caused by congestive heart failure—because a patient who has post-MI LVD with symptomatic heart failure "would be diagnosed as suffering from congestive heart failure under the district court's construction." Although the post-MI-LVD indication on the skinny label recited treating patients "with or without symptomatic heart failure" (i.e., both infringing and non-infringing uses), the court nevertheless found that the combination of the skinny label, expert testimony that the label explicitly instructs administering carvedilol for the patented use, and expert testimony that the post-MI-LVD indication falls within the definition of congestive heart failure "is substantial evidence that supports the jury's findings."

The court further noted that the accused infringer's marketing efforts and press releases showed that the accused infringer encouraged carvedilol sales for the patented use despite the attempted carve-out. For example, the accused infringer marketed its product as an "AB rated therapeutic equivalent to Coreg®," which, "under these limited circumstances, when substantial evidence supports the jury's presumed determination regarding the label's contents, [is] further affirmative evidence supporting the jury's inducement finding." However, the court declined to

go so far as to hold that “an AB rating in a true section viii carve-out (one in which a label was produced that had no infringing indications) would be evidence of inducement.”

In a lengthy dissent, Judge Prost criticized the majority’s opinion for throwing “a wrench into Congress’s design for enabling quick public access to generic versions of unpatented drugs with unpatented uses.” Judge Prost wrote that the majority improperly “glean[ed] intentional encouragement from a label specifically designed to avoid encouragement” and that it “eviscerat[ed] the causation prong of inducement.”

Read the full decision here.
2 Min Read

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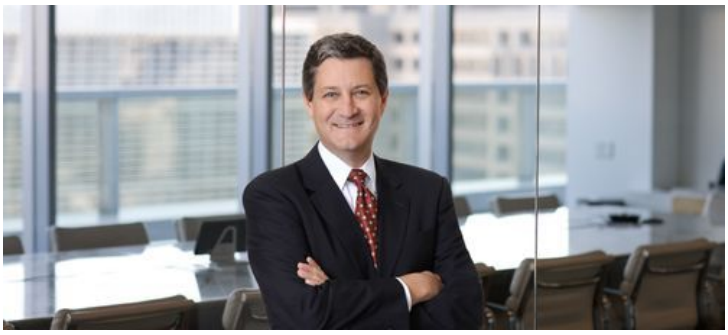

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