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Update: The Saga of the Skinny Label Continues

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On August 5, a split Federal Circuit vacated the district court's ruling of no induced infringement against Teva Pharmaceuticals (Teva) of a GlaxoSmithKline (GSK) patent and reinstated the jury's $235 million patent infringement damages verdict. *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.,* No. 2018-1976 (Fed. Cir. Aug. 5, 2021) at 4. The dispute involved GSK's drug Coreg (carvedilol), having three indications: mild-to-severe chronic heart failure hypertension (CHF), Left Ventricular Dysfunction Following Myocardial Infarction (post-MI LVD), and hypertension. Teva's skinny label of its generic carvedilol product identified only the hypertension and post-MI LVD indications. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 313 F.Supp. 3d 582, 588 (D. Del. 2018).

A skinny (or a carved out) label is a generic pharmaceutical product label that has an unpatented indication and at least one patented indication omitted as compared to the brand counterpart. Upon approval of a skinny label, an ANDA applicant's generic product is able to reach the market before the patent associated with the patented indication expires. Under the Hatch-Waxman Act, an ANDA applicant with a skinny label is not liable for infringement of the patented indication. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1359-60 (Fed. Cir. 2003) ("Congress recognized that a single drug could have more than one indication and yet that ANDA applicant would seek approval for less than all of those indications.").

The dispute between Teva and GSK was whether Teva's label was a skinny label (no infringement) or a partial label (infringement). At oral argument before the Federal Circuit, GSK's counsel argued that Teva's label "was not a skinny label but a partial label" such as the label in *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042 (Fed. Cir. 2011) (inducement found in downward titration language in carved out label because some consumers would inevitably practice AstraZeneca's claimed method). Although not relying on *AstraZeneca*, the Court found "Teva's partial label instructed the method of use claimed in [RE40,000] and thus was not a skinny label." *GSK* at 14. Specifically, the Court found that Dr. McCullough (GSK's expert) testified that the post-MI LVD was "intertwined with heart failure" and Dr. Zusman (Teva's

expert) agreed that a patient with post-MI LVD "would be diagnosed with as suffering from congestive heart failure under the district court's construction." *Id*.

The combination of Teva's partial label, Dr. McCullough's testimony explaining how the partial label led to infringing use and Dr. Zusman's admission "was substantial evidence that support[ed] the jury's finding" of induced infringement. *Id*. at 18. The Court found that the district court had erred in rendering the JMOL and overturned the jury's verdict. The finding of fact for the post-MI LVD portion of Teva's label "was for the jury, not this court or the district court, to resolve." *Id*. at 19.

The Court's ruling seems to favor brand-name drug companies in similar skinny label fights, but the Court warned that generic drug companies needn't fret: "This narrow, case-specific review of substantial evidence does not upset the careful balance struck by the Hatch-Waxman Act regarding section viii carve-outs." *Id*. at 10-11. Time will tell.