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The Saga of the Skinny Label Continues

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On February 9, the October 2020 judgment on induced infringement in *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.,* No. 2018-1976 (Fed. Cir. Feb. 9, 2021) was vacated and its accompanying opinions withdrawn. On February 23, the Court heard oral argument on whether there was substantial evidence to support the jury's verdict of induced infringement during January 8, 2008 through April 30, 2011 ("the skinny label period").

A skinny (or a carved out) label is a pharmaceutical product label that has an unpatented indication and at least one patented indication omitted. 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.[1]

In *GSK v. Teva*, the pharmaceutical product at issue was GSK's drug Coreg (carvedilol) which had three indications: mild-to-severe chronic heart failure hypertension (CHF), Left Ventricular Dysfunction (LVD) and hypertension. Teva's carved out label for its carvedilol product identified only hypertension and LVD as its indications.[2] As Orange Book U.S. Patent No. 5,760,069 ("the '069 patent") claiming CHF had been carved out, Teva received approval of its ANDA in September 2007 and launched its generic carvedilol tablets upon approval.[3] On January 8, 2008, the '069 Patent was reissued to GSK as RE40,000 ("the '000 patent") and also claimed CHF.[4] GSK promptly delisted the '069 Patent from the Orange Book and listed the '000 patent in its place.

In the district court case, the jury found that Teva had induced infringement of claims 1-3 of the '000 patent during the skinny label period of January 8, 2008 through April 30, 2011.[5] However, the district court disagreed. Specifically, the language in the Teva skinny label directed to reducing cardiovascular mortality in patients with LVF was not language that would "encourage doctors to use carvedilol to reduce the risk of death from [CHF]".[6] In addition to Teva's label, GSK also cited to Teva's AB rating and Teva's 2008-2009 marketing information.[7] However, despite this evidence, the district court found

that GSK has not shown that Teva had caused any infringement of the '000 patent during the post-launch period. Specifically, the court found that doctors relied on their experience and GSK marketing to influence their prescribing behavior. Further, there was no evidence that demonstrated that doctors were influenced by a generic's labeling.[8] Since "no direct evidence was presented at trial that any doctor was ever induced to infringe the '000 patent by Teva's label (either skinny or full),"[9] the district court granted Teva's JMOL.

On appeal, however, in October 2020, the Federal Circuit vacated the district court's grant of JMOL and reinstated the jury verdict of induced infringement and damages of $235 million. As noted above, the October 2020 judgment was vacated.

During the February 23, 2021 rehearing, the panel heard testimony on whether Teva had induced infringement of the '000 patent during the time period when Teva had carved out the CHF indication. Teva and many amici had warned that an inducement ruling during the skinny label period would have adverse consequences to the generic industry. However, GSK argued that this was not simply a skinny label case; Teva's carved out label had information that would have led to infringement of GSK's CHF patent. 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).

Practice Note

Teva sold $74 million of carvedilol product during the infringing period. However, it may be liable for $235 million in damages. In pursuing a skinny label strategy to carve out a patented treatment method, aligning the marketing department with patent counsel may be helpful. For example, the press releases could have stated that Teva's product was AB-rated for its labeled uses instead of just saying Teva product was AB-rated without more.

In addition, marketing evidence (including press releases) played a role in the Federal Circuit's decision to reverse the district court's JMOL. A review of outgoing press releases and/or educating the marketing department on skinny label scenarios may be helpful. Aligning the regulatory department with patent counsel may also be helpful. For example, when the FDA asked for the Teva label to add back the CHF indication in 2011, a call to patent counsel would have confirmed that the '000 patent still claimed CHF and therefore continued to provide a basis for a carved out label.

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[1] *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."

[2] *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc*., 313 F.Supp. 3d 582, 588 (D. Del. 2018).

[3] *Id.* at 587.

[4] *Id.* at 586.

[5] *Id.* at 589. January 8, 2008 was the day the '000 patent issued. April 30, 2011 was the last day Teva had a carved out (skinny) label.

[6] *Id.* at 592 n.9.

[7] *Id.* at 593.

[8] *Id.* at 594-95.

[9] *Id.* at 595.