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2/5 UPDATE: GSK v. Teva: The Skinny On Induced Infringement And Label Carve-Outs

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On January 13, we originally posted on this topic. An update posted on February 10 provides the most recent update on this matter.

The Federal Circuit invited GSK to respond to Teva's *en banc* petition, and on January 29 respond it did. GSK made clear its position that the Court's October 2, 2020 opinion reversing the JMOL and remanding for entry of the jury verdict does not spell "doomsday" for section viii carveouts. [1] GSK stated that the "case does not implicate the fate of section viii carve-outs" and does not "upset the legal framework for evaluating them." [2] Thus, GSK takes the position that no "exceptional circumstances" exist to justify Teva's petition for *en banc* review.[3]

GSK argued the jury was properly instructed and found Teva induced infringement by failing to adequately carve out the patented method of use from the label of its AB-rated generic product.[4] GSK further argued that Teva's "partial label was not a true section viii carve-out" under the Hatch-Waxman Act. [5] GSK also pointed out the significance of the AB rating of Teva's product and promotion thereof in the induced infringement analysis and jury instructions.[6] In the opinion, the Court explained "[t]he jury was correctly instructed that it could find inducement if Teva 'continued to take an action . . . intending to cause the physicians to directly infringe by administering Teva's carvedilol product', including affirmative promotion as an AB-rated generic equivalent of COREG®.[7]

Citing *AstraZeneca LP v. Apotex, Inc.*, where the Court upheld a finding of induced infringement based on a generic "partial label" that failed to "actually carve out the patented use," GSK argued the section viii carve-out framework set forth in the Hatch-Waxman Act did not collapse and will not collapse here.[8] Rather, GSK contends generic companies can still "continue to enjoy the carve-out statute's protection;" however, if a generic does not carve out enough, section viii does not serve as "a shield against [induced infringement] liability." [9]

We expect a decision regarding the petition for *en banc* review shortly and anticipate Teva will file a petition for certiorari for Supreme Court review if the petition is denied. Please contact the authors with any questions and stay tuned for updates regarding this important topic.

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Footnotes

[1] *See* GSK's Response Brief to Petition for Rehearing En Banc at 14, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, No. 18-1976 (Fed. Cir. Jan. 29, 2021), Dkt. 178.

[2] *Id.* at 1.

[3] *Id.* at 7.

[4] *Id.* at 9-10, 14-15.

[5] *Id.* at 5, 8.

[6] *Id.* at 9-10.

[7] *See GlaxoSmithKline LLC v. Teva Pharms USA, Inc.*, 976 F.3d 1347, 1355 (Fed. Cir. 2020).

[8] GSK's Response Brief, *supra* note 1, at 14 (citing 633 F.3d 1042, 1056 (Fed. Cir. 2010)).

[9] *Id.* at 15.