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Client Alert

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FDA and Life Sciences

GSK v. Teva and Induced Infringement by AB-Rated Generics: Where are we now?

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The Federal Circuit's October 2020 split decision in *GSK v. Teva*[1] made waves throughout the pharmaceutical industry and among Hatch-Waxman litigators. In the broadest reading, some see the majority opinion as rendering any manufacturer of a marketed "AB-rated" generic drug liable for induced infringement of patents covering any of the brand products' FDA-approved indications – even where the generic's labeling "carved out" such an indication to escape infringement under the "section viii" provision of Hatch-Waxman.[2]

GSK v. Teva is now headed to a Federal Circuit panel rehearing (not *en banc* review) on February 23, and the industry and practitioners are watching closely. But recent developments suggest that the Federal Circuit might now avoid the hotly-debated legal question of whether a generic with a fully "carved-out" indication might induce infringement solely by touting its "AB-rating." Rather, there are signs that the majority might refine its original ruling by focusing on factual issues – including whether the jury had substantial evidence to find that Teva's label was insufficiently "carved-out," and thus still encouraged use of Teva's product for the patented indication.

In our update below, we track these developments in *GSK v. Teva*, and show how the dispute has evolved as it is teed up for panel rehearing on February 23. We also review the latest happenings in *Amarin v. Hikma*[3] – another "must-watch" brand vs. generic carve-out dispute percolating in the District of Delaware – which mirrors *GSK v. Teva* in some respects, and also introduces new twists. Stay tuned for our King & Spalding updates as we keep a close eye on breaking news.

GSK V. TEVA (FED. CIR.) – THE ROAD TO PANEL REHEARING

To recap: the dispute in *GSK v. Teva* concerns whether Teva's marketing of an AB-rated generic version of GSK's COREG® (carvedilol) induced infringement of GSK's '000 patent for "decreasing mortality caused by congestive heart failure," during a period (2008-2011) when Teva's

generic labeling allegedly "carved out" certain language from GSK's COREG® labeling regarding treatment of "mild-to-severe chronic heart failure."[4] A jury in the District of Delaware found that Teva did so infringe; and Chief Judge Stark granted Teva's motion for JMOL on the grounds that GSK allegedly failed to prove causation between Teva's acts and infringement by physicians.[5]

In a 2-1 Federal Circuit opinion last October, the panel majority (Judges Newman and Moore) reinstated the jury's verdict – finding "substantial evidence" of inducement in "promotional materials, press releases, product catalogs, the FDA labels, and testimony of witnesses from both sides."[6] The majority's opinion focused significantly on evidence that Teva marketed its product as an "AB Rated generic of Coreg® Tablets," and testimony that physicians rely on such statements to prescribe generics for all indicated uses of the brand product.[7] Teva's December 2, 2020 petition for panel rehearing or *en banc* review ("Teva's Petition"), and the supporting briefs of multiple generic industry *amici*, largely echoed Judge Prost's dissenting position: that the majority opinion purportedly would "nullify" the statutory "section viii" provision under Hatch-Waxman, by holding Teva liable for induced infringement of patents covering an allegedly "carved-out" indication.[8]

Recent developments, however, suggest that the dispute in *GSK v. Teva* may be shifting away from the larger statutory and policy questions regarding "section viii" and "AB-rated" generics – and towards a narrower, factual dispute regarding the contents of Teva's 2008-2011 generic labeling. In its January 29, 2021 response to Teva's Petition ("GSK's Petition Response"), GSK argued that Teva did ***not*** actually "carve out" the patented "congestive heart failure" indication – but rather "left in" language sufficient for the jury to find "run-of-the-mill" induced infringement based on express "encourage[ment]" by Teva's label itself.[9] GSK further contended "that finding is implicit in, and necessary to, [the panel majority's] decision," which "noted [Teva's] label provided evidence from which a jury could conclude Teva encouraged the patented use."[10] Accordingly, GSK dismissed Teva's concerns of "section viii nullification" as an unrealistic "doomsday scenario," contending that the majority opinion "reiterate[d] that generics who wish to [enter the market with partial labels] must comply with section viii by completely carving out the patented use."[11] According to GSK: "As long as generics fully carve out the patented use, they can continue to enjoy the carve-out statute's protection."[12]

And on February 9, rather than granting *en banc* review, the Federal Circuit granted a panel rehearing for February 23, 2021, on the "limited" issue of "whether there is substantial evidence to support the jury's verdict of induced infringement" for the "partial label" period between 2008 and 2011.[13] While the outcome remains to be seen, it is possible that the panel majority may use the rehearing to refine its original opinion on the evidentiary issues raised by GSK – *i.e.*, whether Teva's label was insufficiently "carved-out" to avoid inducement – rather than focus on the broader legal questions regarding induced infringement of completely "carved-out" uses that Teva and its *amici* urged for *en banc* review.

AMARIN V. HIKMA (D. DEL.) – *GSK V. TEVA* REDUX, AND SOMETHING NEW?

Another closely-watched case in light of *GSK v. Teva* is the ongoing brand vs. generic patent dispute in *Amarin v. Hikma*, in early stages in the District of Delaware. Like *GSK v. Teva*, *Amarin v. Hikma* concerns (1) a brand's assertion of induced infringement allegations against a marketed, AB-rated generic version of a brand product – Hikma's generic version of Amarin's branded VASCEPA® (icosapent ethyl), and (2) the generic's contention that it has avoided induced infringement of the brand's asserted patents by allegedly "carving out" the patented indication from its generic label.[14]

In large part, the dispute between Amarin and Hikma tracks the current state of the *GSK v. Teva* dispute as it heads to panel rehearing. In its January 27, 2021 Motion to Dismiss, Hikma contends that it had fully carved out the patented "Cardiovascular [CV] Indication" from its label (retaining only a "Severe Hypertriglyceridemia" indication litigated in an earlier trial[15]), and thus cannot induce infringement as a matter of law.[16] In turn, Amarin on February 10 opposed Hikma's motion to dismiss ("Amarin's Opposition") with arguments tracking GSK's Petition Response: that, as alleged in Amarin's amended complaint, Hikma's "not-skinny-enough drug label" retained language sufficient to show induced infringement of Amarin's patents to the CV Indication[17] – similar to Apotex's ineffective carve-out for PULMICORT®

RESPULES® in the Federal Circuit's 2010 *AstraZeneca v. Apotex* decision.[18] Interestingly, Amarin also argues that Hikma's label induces infringement by ***removing*** the statement that the effects of its product "on cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia ***has not been determined***" – language that Amarin removed from its branded VASCEPA® label only when it added the CV Indication.[19]

Notably, neither Amarin nor Hikma appears to contend that *GSK v. Teva* represents a fundamental change in law regarding induced infringement by AB-rated generic drug products. Rather, Amarin maintains that its inducement claim relies substantially on Hikma's "not-skinny-enough" label (including Hikma's removal of allegedly limiting language), and is ***not*** "based just on Hikma's reference[s] to its AB rating."[20] Hikma alleges that its public statements actually undermine Amarin's inducement claim, pointing to Hikma's November 2020 press release stating that its newly-launched generic product "is not approved for any other indication for the reference listed drug VASCEPA®"[21] Amarin, in turn, contends that Hikma's alleged public disavowal of the CV Indication (1) "came too late" in light of Hikma's "lay[ing] the groundwork for others' infringement" with earlier press releases allegedly referencing the CV Indication;[22] and in any case (2) "ignores the problem with [Hikma's] label."[23]

Amarin has also added a new twist to potential inducement liability for a "carved-out" AB-rated generic product, by suing the health insurance provider Health Net.[24] In its January 25, 2021 Amended Complaint, Amarin alleges that Health Net is liable for inducing infringement of Amarin's CV Indication patents because (1) Health Net added Hikma's generic product to its formularies, at a more favorable "tier" than VASCEPA®, (2) Health Net "covers and directs payment" for Hikma's generic product for all approved indications of VASCEPA®, and (3) Health Net makes no distinction on its formulary listing for Hikma's generic product with respect to its FDA-approved indication and the unapproved CV Indication.[25] Health Net's answer or other response to Amarin's Amended Complaint is currently due on February 16, 2021 – so stay tuned for our updates on further developments.

[1] *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 976 F.3d 1347 (Fed. Cir. 2020)
[2] *See, e.g.*, *GSK*, 976 F.3d at 1365-67 (Prost, J., dissenting); *GlaxoSmithKline LLC et al. v. Teva Pharms. USA, Inc.*, No. 18-1976 ("*GSK v. Teva* Docket"), D.I. 116 at 10-14 (Fed. Cir. Dec. 2, 2020) ("Teva's Petition").
[3] *Amarin Pharma, Inc. et al. v. Hikma Pharms. USA Inc. et al.*, C.A. No. 20-1630-RGA (D. Del.) ("*Amarin v. Hikma* Docket")
[4] *See generally GSK*, 976 F.3d at 1349-56.
[5] *See id.* at 1350-51.
[6] *See id.* at 1355-56.
[7] *See id.* at 1350, 1353-56.
[8] *Supra* note 2; *see also, e.g.*, *GSK v. Teva* Docket, D.I. 164 at 7-10 (Fed. Cir. Dec. 29, 2020) (amicus brief of the Association for Accessible Medicines); *GSK v. Teva* Docket, D.I. 169 at 7-11 (Fed. Cir. Dec. 30, 2020) (amicus brief of Mylan Pharmaceuticals Inc.)
[9] *See GSK v. Teva* Docket, D.I. 178 at 2, 4-6, 13-17 (Fed. Cir. Jan. 29, 2021) ("GSK's Petition Response").
[10] *See id.* at 13-15
[11] *See id.* at 14-17
[12] *See id.* at 15
[13] *GSK v. Teva* Docket, D.I. 181 (Fed. Cir. Feb. 9, 2021)
[14] *See Amarin v. Hikma* Docket, D.I. 17, ¶¶ 92-135 (D. Del. Jan. 25, 2021) ("Amarin's Amended Complaint"); *see generally Amarin v. Hikma* Docket, D.I. 20 (D. Del. Jan. 27, 2021) ("Hikma's Motion to Dismiss")
[15] *See generally Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 449 F. Supp. 3d. 967 (D. Nev. 2020), *aff'd*, 819 Fed. App'x 932 (Fed. Cir. 2020)
[16] *See* Hikma's Motion to Dismiss, at 2-3, 7, 15-18
[17] *See Amarin v. Hikma* Docket, D.I. 22 at 1-2, 6-8, 13-15, 19 ("Amarin's Opposition") (citing Amarin's Amended Complaint, ¶¶ 103-31, 134)
[18] *See* Amarin's Opposition at 13-15 (citing *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042 (Fed. Cir. 2010)).
[19] *See* Amarin's Opposition at 5, 8, 10, 13-14, 18, 20.
[20] *See id.* at 20.
[21] *See* Hikma's Motion to Dismiss at 3-4, 8, 20
[22] *See* Amarin's Opposition at 15
[23] *See id.*
[24] *See generally* Amarin's Amended Complaint, ¶¶ 137-162
[25] *See id.*

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