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Carve outs and Causation: Moving Away From Hypothetical Hatch-Waxman Infringement

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The Hatch-Waxman Act allows the FDA to permit a generic version of a branded product, which is partially patent protected, to come to market if the generic manufacturer "carves out" the patent-protected indication from its label. The scope of protection from a finding of induced infringement afforded to generic manufacturers by this "skinny label" provision has, however, engendered significant debate. In two recent decisions, the U.S. Court of Appeals for the Federal Circuit and the Delaware District Court have addressed this very important issue. Both decisions are particularly noteworthy as they do not involve the more typical Hatch-Waxman case, which requires an analysis of a *hypothetical* post-FDA approval world wherein the generic product can be marketed. Instead, the generic products at issue in these cases were FDA approved and being sold, and that has triggered a discussion regarding causation and opened the doors to novel claims of infringement.

GSK v. Teva

GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., ___ F.3d ___, Nos. 2018-1074, 2018-2023 (Fed. Cir. Aug. 5, 2021), is the second 2-1 precedential opinion issued by the Federal Circuit reviving a $235 million verdict against Teva for inducing infringement of GSK's heart disease drug carvedilol, a beta-blocker sold as Coreg®. Coreg® is FDA-approved for three indications: (1) treatment of hypertension, (2) treatment of congestive heart failure ("CHF"), and (3) to reduce cardiovascular mortality in patients suffering from left ventricular dysfunction following a myocardial infarction ("the post-MI LVD indication"). Teva obtained FDA approval for a generic carvedilol product, which it launched together with a label containing two of the three approved indications: hypertension and post-MI LVD. Teva, however, marketed its generic as: "indicated for treatment of *heart failure* and hypertension," the "Generic version of [GSK's] *cardiovascular* agent Coreg®," and an "AB-rated generic equivalent of [GSK's] Coreg® Tablets" (emphasis added).

GSK sued Teva in the District of Delaware alleging that Teva induced infringement of U.S. Patent No. RE40,000, which claims a method of using carvedilol for "decreasing mortality caused by [CHF]." Teva denied infringing the patent "because it had 'carved

out' the indication and prescribing information for treatment of [CHF]." The jury disagreed, finding induced infringement and awarding GSK substantial damages. The verdict was overturned by the district court on the grounds that "GSK failed to prove that Teva's alleged inducement, as opposed to other factors, *actually caused* physicians to directly infringe by prescribing generic carvedilol for the treatment of mild to severe CHF" (emphasis added).

GSK appealed and, in its first precedential decision in this case, the Federal Circuit revived the jury verdict. That decision prompted manufacturers of both branded and generic drugs, fifty-seven law professors, and Congressman Waxman, to raise concerns—including that the decision could be read as imposing liability on generics manufactures "for merely marketing and selling under a 'skinny' label . . . , or for merely noting (without mentioning any infringing uses) that FDA had rated a product as therapeutically equivalent to a brand-name drug." The Federal Circuit agreed to rehear the case.

In its recent decision, the majority of the Federal Circuit reviewed its precedents, noting that "[w]hen a plaintiff relies on a drug's label accompanying the marketing of a drug to prove intent [to induce infringement], '[t]he label must encourage, recommend, or promote infringement.'" In the majority's opinion, GSK had met this burden by proving that Teva's *purported* skinny label failed to fully carve out the patent-protected method of using carvedilol for "decreasing mortality caused by [CHF]." Instead, Teva's label could be read to contain all the limitations of the patent claims in the post-MI LVD indication, including that "Carvediol is indicated to reduce *cardiovascular* mortality," and sections that either immediately followed (the Dosage and Administration section) or were expressly referenced by that indication (the Clinical Studies section). In addition, according to the majority, Teva's marketing materials, which promoted the product for the treatment of "heart failure" and as an "AB-rated generic equivalent" of Coreg®, were sufficient to show an affirmative intent to induce infringement. The majority made clear, however, that it was not holding "that an AB rating in a *true* section viii carve-out . . . would be evidence of inducement." Rather, "Teva's representation of an AB rating" showed intent to induce because it "would point physicians to its partial label [with its disclosure of the relevant limitations in the claims]."

In dissent, Judge Prost observed that the majority "never meaningfully engaged with the legal distinction between encouraging, recommending, or promoting an infringing use and describing it." Moreover, the dissent argued that by relying on a "passing observation" that the Federal Circuit has "affirmed induced infringement verdicts based on circumstantial evidence of inducement (e.g., advertisements. . .) directed to a class of direct infringers (e.g., customers. . .) without requiring hard proof that any . . . direct infringer was *actually* persuaded to infringe by that material," the majority "eviscerates the causation requirement" of patent infringement (emphasis added).

This issue of causation was recently at the center of a health insurance provider's motion to dismiss claims based on a "novel theory" for induced infringement, discussed below.

Amarin v. Hikma

Amarin Pharma, Inc. v. Hikma Pharms. USA Inc., No. 20-1630 (D. Del. filed Nov. 30, 2020), concerns Amarin's product Vascepa®, which is FDA-approved for the treatment of severe hypertriglyceridemia ("the SH indication") and cardiovascular risk reduction ("the CV indication"). Hikma obtained FDA approval and launched its generic version of Vascepa® together with a label containing one of the two approved indications, carving out the patent-protected CV indication. Amarin brought suit against Hikma and Health Net, a health insurance provider, for induced infringement.

Notably, Amarin "allege[s] that the way Health Net has set up its approval and payment process for Amarin's product and Hikma's generic version amounts to *active encouragement* to use Hikma's generic version for the patented indication" (emphasis added). According to Amarin, Health Net knows when a particular beneficiary is using the generic version of Vascepa® for the patented CV indication "because Health Net's prior authorization process requires the beneficiary's provider to submit documentation supporting the use for which it has been prescribed." And, despite this knowledge, Health Net provides coverage and payment for the generic drug even when its use is infringing. Health Net allegedly encourages this infringing use by "requir[ing] its beneficiaries to pay a higher copay for Vascepa than for Hikma's generic, even when [the generic drug] has been prescribed for the infringing/CV use."

Health Net moved to dismiss these claims for lack of causation, arguing that "despite knowledge of infringement by its beneficiaries and their providers," it could not be found liable because its actions, "do not, in fact, influence the decisions of beneficiaries, pharmacists, and medical providers to use, dispense, and prescribe Hikma's generic product in an infringing way." Despite acknowledging that "[n]either side has cited any case in which a health insurer has been found liable to a pharmaceutical company for inducing infringement of a drug method of use patent," the Magistrate Judge recommended denying Health Net's motion to dismiss. Viewing the allegations in the light most favorable to Amarin, as is the applicable standard, and given the absence of precedent to the contrary, the Magistrate Judge could not conclude that Amarin's theory is so implausible as to require dismissal on the pleadings.

Whether this novel claim against a health insurer will succeed on the merits remains an open question, but the case will at least for now move forward to discovery.

Concluding Remarks

Both *GSK* and *Amarin* illustrate the struggles courts are having with Hatch-Waxman cases involving generic products actually being marketed. The legal ambiguities relating to causation are allowing for novel theories of infringement, which will undoubtedly continue to evolve.

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