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GSK v. Teva: Federal Circuit Issues New Opinion Analyzing Induced Infringement

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On August 5, 2021, the Federal Circuit withdrew its October 2020 opinion in *GSK v. Teva*, summarized in this post on induced infringement of method-of-treatment claims, and issued an opinion that reiterated the prior holding but sought to clarify its reasoning. *GlaxoSmithKline v. Teva*. Specifically, the majority stated that a generic manufacturer's touting of AB equivalence to a brand drug is generally not evidence of intent to induce infringement—but in the specific facts of this case it did support inducement, because the Court found ample evidence tying claim limitations to statements in Teva's label even though the patented method was omitted as a distinct indication. The Court also found that Teva's advertising statements regarding treating "heart failure" evidenced intent to induce physicians to prescribe the drug to treat CHF.

The reissued opinion suggests that an FDA approved label purporting to omit patent protected information is not a safe harbor from a finding of intent to induce infringement. The Court found that other language in the label may still induce physicians to prescribe a drug in an infringing manner—especially if coupled with extrinsic statements that emphasize equivalence to the branded drug, or promote uses with language broad enough to potentially overlap with the protected methods.

Background

The asserted patent covered a method of administering carvedilol to decrease mortality caused by congestive heart failure (CHF). Teva originally carved out the CHF indication from its product label—but the FDA later required Teva to amend its label to be identical to the label for the reference listed drug, Coreg, which included this indication. After a jury trial before Judge Stark in the District of Delaware, Teva moved for a judgment as a matter of law to reverse the jury's finding of induced infringement during both the period when Teva's label included the CHF indication and the period when this indication was carved out. Judge Stark granted Teva's motion, holding that the plaintiff must prove that the defendant's alleged inducement—as opposed to other factors—actually caused physicians to prescribe Teva's product in an infringing manner. Judge Stark noted that there was ample post-launch evidence of activities not involving Teva that caused doctors to prescribe Teva's generic product in an infringing manner, including: treatment guidelines; GSK's own label and promotional activity; and expert testimony that doctors relied on this evidence and their own experience when deciding how to prescribe Teva's drug.

GSK appealed, arguing that the district court failed to properly consider its evidence of Teva's press releases and promotional materials—which touted the drug as "equivalent" or "AB-rated" to Coreg. On October 2, 2020, the Federal Circuit sided with GSK in a 2-1 decision, holding that "precedent makes clear when the provider of an identical product knows of and markets the same product for intended direct infringing activity, the criteria of induced infringement are met." *GlaxoSmithKline v. Teva Pharm. USA, Inc.*. The majority found that Teva's press releases and marketing communications provided sufficient circumstantial evidence to show that Teva took active steps to encourage the infringing use even during the period where the CHF indication was carved out of the label.

The October 2020 holding thus suggested that marketing of a generic drug as "AB-rated" or "equivalent" to a reference listed drug may lead to a finding of inducement, even where the patented use has been carved out of the generic label. This potential interpretation raised some industry concerns that the holding might conflict with Congress's intent in allowing label carve outs for generic drugs (a concern echoed in the dissent penned by Judge Prost). Accordingly, the Federal Circuit agreed to rehear the case.

The August 2021 Opinion

On August 5, 2021, the Federal Circuit withdrew its prior opinion and issued a new opinion—once again written by a 2-1 majority, and once again vacating the district court's grant of JMOL of no induced infringement, reinstating the jury verdict, and remanding for appropriate further proceedings.

In the new opinion, the majority clarified and focused its analysis on the language of the label itself. The Court explained that "GSK provided substantial evidence that Teva's partial label instructed the method of use claimed in the [patent] and thus was not a skinny label." *GlaxoSmithKline v. Teva*, No. 18-1976, slip op. at 14 (Fed. Cir. Aug. 5, 2021). The majority pointed to GSK's cardiology expert, who testified that the statement in Teva's partial label—"Carvedilol is indicated to reduce cardiovascular mortality"—satisfied the claim limitation that "deceasing mortality [is] caused by congestive heart failure" and, further, that the label's reference to "post-myocardial infarction with left ventricular dysfunction" (post-MI LVD) "is intertwined with heart failure." *Id.* at 13.

The Court further held that GSK's expert tied other sections of Teva's partial label to the remaining dosage and co-administration limitations. Specifically, GSK's expert testified that the Dosage and Administration section taught the daily dosage and dosage maintenance limitations of the claims, and the Clinical Studies section (referenced by the post-MI LVD indication) showed that study patients were co-administered ACE inhibitors and diuretics, which taught the remaining co-administration limitation. *Id.* at 14. The Court concluded that "substantial evidence supports the finding that Teva's partial label was evidence Teva instructed physicians to use its carvedilol in an infringing way," and that "GSK presented evidence that doctors read and consider labels in making prescribing decisions." *Id.* at 32-33.

The Court then discussed evidence extrinsic to the label, particularly Teva's advertising and promotional efforts, concluding: "Teva's marketing materials guided doctors to the label and to its website promoting the patented use [and] that Teva issued press releases encouraging doctors to prescribe carvedilol for the patented use." *Id*. at 32. In particular, the Court pointed to Teva's statements that "Carvedilol Tablets are the AB rated generic equivalent of GlaxoSmithKline's Coreg® Tablets and are indicated for treatment of heart failure and hypertension." *Id*. at 28. The Court emphasized this reference to heart failure, which did not differentiate between CHF and heart failure caused by post-MI LVD. However, the Court did clarify that "we do not hold that an AB rating in a true section viii carve-out (one in which a label was produced that had no infringing indications) would be evidence of inducement." *Id.* at 28, n.7. The Court stated that, nevertheless, "[i]n this case, Teva's representation of AB rating would point physicians to its partial label, which, for the reasons above, the jury was free to credit as evidence of induced infringement." *Id.*

The new opinion also touched on the related issue of equitable estoppel—specifically, that GSK made representations to the FDA regarding what language in the Coreg label corresponded to patented uses, and that Teva detrimentally relied on these statements in crafting its partial label. However, the issue was not decided by the district court, so it will be interesting to see how it is handled on remand, if at all.

Takeaways

The August 2021 opinion is notable for several reasons. First, as stated above, it appears that generic manufacturers may not be able to rely on FDA-approved label carve outs as a safe harbor from a showing of intent to induce infringement. Other sections of the generic product label may nevertheless still provide physicians with information needed to practice the claimed method, especially if combined with statements made when marketing and promoting the drug's uses.

Additionally, the August 2021 opinion clarifies that a representation of equivalence or an AB rating, without more, is not evidence of intent to induce infringement. However, the Court noted that under the circumstances of this case, GSK's expert provided substantial evidence that even Teva's partial label contained sufficient language and information to teach the patented method of treating CHF. The Court also emphasized that there was ample uncontroverted evidence that physicians look to the label when making prescribing decisions, and that Teva's marketing statements touting treating "heart failure" of unspecified origin, and its drug's equivalence to Coreg, provided further evidence of intent to induce infringement.

The holding highlights, in the context of induced infringement, the importance of the totality of the label and extrinsic statements pertaining to the uses and efficacy of a drug product. Expressly omitting the patented indication from the Indications and Usage section may not mean that the label cannot be used by the patent owner to show intent to induce infringement. Other sections of the label may show intent to induce infringement if the language in those sections is logically tied to the patented method. Additionally, extrinsic statements, such as marketing materials, FDA communications, and the like, may inform whether a physician would prescribe the drug in an infringing manner. Generic and biosimilar manufacturers may thus consider whether additional label carve outs besides those in the Indications and Usage section are necessary or possible, and may also consider closely coordinating efforts between legal, regulatory, and business development groups to avoid extrinsic statements that could show intent to induce infringement. Reference product sponsors may likewise be keen to seize on such statements, and may also consider adding information related to claim limitations throughout the label in order to counter any carve out strategy.

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