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Client Alert: GSK v. Teva – Induced Infringement – Are "Skinny Labels" Still Viable?

by David M. Knapp

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On October 2, 2020, the Federal Circuit reinstated a $235.5 million jury verdict against generic drug manufacturer Teva, for the sale of its generic carvedilol product. *In GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.,* Nos. 2018-1976, 2018-2023 (Fed. Cir. 2020), the Federal Circuit ruled that Teva's marketing of their generic of GlaxoSmithKline's (GSK) beta-blocker Coreg® induced infringement of GSK's patent, despite Teva's product having been marketed under a "skinny label" that did not recite the specific indication covered by GSK's patent. This Federal Circuit decision has the potential to reshape how generic pharmaceutical manufacturers approach skinny labeling of generics for non-patented indications.

Teva received United States Food and Drug Administration (FDA) approval to market its generic carvedilol in 2007, following the expiration of GSK's compound patent (US 4,503,067) covering carvedilol, but prior to expiration of GSK's method patent (US 5,760,069), which was directed to a method of decreasing mortality caused by congestive heart failure by administering a carvedilol in combination with one or more additional agents selected from an angiotensin converting enzyme (ACE) inhibitor, a diuretic, and digoxin. The '069 patent was listed in the orange book for "decreasing mortality caused by congestive heart failure," and the combination was approved under the brand name Coreg®.

Teva went to market with a skinny label, which only recited the non-patented indications of 1) left ventricular dysfunction following myocardial infarction, and 2) hypertension, and did not list as an indication congestive heart failure. GSK's patent for treatment of congestive heart failure was later re-issued as RE40,000 (the '000 patent).

In 2011, FDA required Teva to amend its label to be identical in content to the approved Coreg® labeling, and Teva complied, including the indication for treatment of congestive heart failure. In 2014, GSK filed suit against Teva for infringement of the '000 patent. GSK's suit alleged Teva induced infringement of the '000 patent, including during the period prior to Teva's amendment of its label to include the indication of congestive heart failure.

In addition to raising defenses of patent invalidity, Teva argued it had carved out from its initial label the indication and prescribing information for treatment of congestive heart failure, citing the carve-out authorization in 21 U.S.C. § 355(j)(2)(A)(viii), and therefore Teva could not be found to induce prescribing physicians to infringe the '000 patent, at least not before Teva amended its label to include all of the information that the FDA had approved for Coreg®. A jury disagreed, finding Teva had induced infringement of the '000 patent, including during the period of time prior to Teva's amendment of its label, i.e., the skinny label period, and awarded damages of lost profits and royalties totaling $235,510,000.

The District Court granted Teva's motion for JMOL, stating the verdict of induced infringement was not supported by substantial evidence because GSK failed to prove by a preponderance of evidence that "Teva's alleged inducement, as opposed to other factors, actually caused the physicians to directly infringe" by prescribing Teva's generic carvedilol for the treatment of congestive heart failure. The District Court concluded many sources of information were available to prescribing physicians prior to Teva's marketing of a generic product that would have informed them about the uses of carvedilol, such as GSK's Coreg® label and marketing materials, as well as professional guidelines and publications. The District Court concluded a reasonable factfinder could only have found these alternative, non-Teva associated sources of information were what caused the doctors to prescribe Teva's carvedilol for an infringing use, and that Teva was therefore not liable for induced infringement.

GSK appealed the District Court's decision to the Court of Appeals for the Federal Circuit, and in a decision authored by Circuit Judge Newman and Circuit Judge Moore, the Federal Circuit reversed the District Court's decision on JMOL.

In its decision, the Federal Circuit found "ample record evidence of promotional materials, press releases, product catalogs, the FDA labels, and testimony of witnesses . . . to support the jury verdict of inducement to infringe the designated claims for the period of the '000 reissue patent." Among the information that had been presented to the jury that the Federal Circuit found persuasive was Teva's label, which referred to its carvedilol tablets as AB-rated equivalents of the GSK Coreg® tablets, and that Teva's website characterized its carvedilol product as a generic of Coreg® tablets. The Court also noted witness testimony that cardiologists are reliant on information provided by generic producers, including their product catalogs and website, and that Teva's announcement of a generic of Coreg® was an indication that physicians should be able to prescribe the generic for the same indications as Coreg®, i.e, heart failure. The Court also pointed to witness testimony that "the AB-rating means that 'if the generic drug is used in accordance with its label, you would expect it to have the same clinical effect' as the brand drug." According to the Federal Circuit, this information amounted to substantial evidence which could support the jury's verdict of Teva's inducement to infringe the '000 patent. The Federal Circuit's decisions also confirmed the jury finding of damages.

In a lengthy dissent, Chief Judge Prost argued the majority opinion undermines the balance of patent rights and the speedy introduction of generics upon patent expiration by allowing a drug marketed for unpatented uses to give rise to liability for inducement and by permitting an award of patent damages where causation has not been shown. Prost noted Congress provided for skinny labels for exactly these circumstances under U.S.C. § 355(j)(2)(A)(viii). She also warned the decision "nullifies Congress's statutory provision for skinny labels—creating liability for inducement where there should be none." Prost concluded, "Teva did everything right—proceeding precisely as Congress contemplated," launching its low-cost generic for unpatented uses using a skinny label, and not encouraging doctors to use its generic to practice the one still-patented use. Prost also noted that despite following established practice, Teva ended up owing far more in damages than it earned in revenue from its sale of generic carvedilol.

Conclusion

This case will certainly be one to watch for all pharmaceutical companies. Attorneys for both parties involved have indicated they expect an en banc opinion and potentially a Supreme Court opinion on this case. With that in mind, drug manufacturers will want to even more carefully consider whether and how to pursue skinny labels for non-patented indications, in addition to how and whether to advertise products currently marketed with skinny labels. Following the letter of the statutory provision for skinny labels may no longer be enough to avoid litigation relating to or a finding of induced infringement.

If you have any questions, contact David Knapp or another member of Freeborn's Intellectual Property Team.

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David's practice focuses on intellectual property enforcement and defense and intellectual property portfolio management. David has developed patent portfolios in technical fields such as biotechnology, pharmaceuticals, agrichemicals, medical diagnostics, and software. David also advises clients on intellectual property risk management, including patent portfolio due diligence, patent infringement and validity opinions, and freedom-to-operate analyses.

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