BRINKS GILSON & LIONE
100 YEARS OF IP LAW

THINK FORWARD

Federal Circuit Opinion on Heart Medication May Raise Generics' Blood Pressure

By Joshua Smith, Yuezhong Feng

October 08, 2020

***GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.*, no. 2018-1976 (Fed. Cir. Oct. 2, 2020)**

Under some circumstances, a generic manufacturer can be found liable for induced infringement of patented treatments using that drug, even when the generic manufacturer only markets it for unpatented treatments while omitting the patented treatments.

Background - Heart Health History

In the 1980's, GlaxoSmithKline LLC ("GSK") developed and released Coreg, its branded version of carvedilol, as a treatment for hypertension. In the 90's, after further research, scientists discovered its efficacy in treating congestive heart failure. GSK patented the use of carvedilol to treat heart failure, which ultimately resulted in GSK's reissue patent number RE40,000 ('000 patent) in 2008.

Teva Pharmaceuticals USA, Inc. ("Teva") developed, marketed, and released its generic carvedilol as an equivalent to GSK's Coreg in 2007 (following the expiration of GSK's original patent from the 80's covering the general formula). In its original 2007 "skinny label," however, Teva specifically omitted reference to its generic version as a treatment for heart failure. In 2011, the FDA required Teva to revise the labeling to include all the content of the branded GSK Coreg labeling, including the indication for treatment of heart failure (the subject of the '000 reissue patent claims).

In 2014, GSK sued Teva for infringement of its '000 patent. At the district level, the jury found the claims valid and infringed by inducement, awarding damages of $235 million. However, after the jury verdict, the District Court granted Teva's motion for judgment of non-infringement as a matter of law ("JMOL"), stating the evidence was legally insufficient to show Teva induced infringement.

The Majority Opinion - A Bitter Pill for Generics

On review, the majority (Judges Newman and Moore) vacated the District Court's JMOL and remanded to reinstate the jury verdicts of infringement and damages. In particular, the majority found that there was substantial evidence to support the jury's verdict of inducement to infringe.

The majority focused on Teva's marketing materials, press releases, and product catalogs indicating its carvedilol is an "AB Rated generic of Coreg(R) Tablets" (i.e., it is "therapeutically equivalent"). Additionally, the majority discussed the expert testimony that prescribing doctors regularly rely on such materials from generic producers, and that those materials lead doctors to believe that Teva's generic carvedilol could be used for heart failure. Additionally, the majority discussed the FDA labels, which were revised in 2011 (by order of the FDA) to include all the content of the branded GSK Coreg

labeling, including the indication for treatment of heart failure (the subject of the '000 reissue patent claims). In reviewing this material, the majority agreed with GSK that the jury verdict was supported by substantial evidence.

Teva argued that it was not liable for induced infringement because it specifically carved out reference to heart failure from its first 2007 "skinny label." However, GSK's witnesses had explained that, despite this omission from the 2007 label, Teva's other materials touting the "AB Rating" lead doctors to believe that it could be used for heart failure.

Further, Teva had argued that doctors already knew how to use carvedilol to treat heart failure, and thus infringement was not "caused" by Teva simply listing it as an AB Rated generic to GSK's Coreg. However, the majority found that the jury's verdict was still supported by substantial evidence, and found that the District Court had overstepped.

Chief Judge Prost's Dissent - Heartburn

The Chief Judge agreed with the District Court's JMOL that there was legally insufficient evidence to show that Teva actually caused doctors to directly infringe the '000 patent, whether using the original "skinny label," or the later FDA-mandated full label.

Importantly, regarding the original "skinny label", the Chief Judge indicated that Congress provided for such "skinny labels" for exactly these circumstances (*see* 21 U.S.C. § 355(j)(2)(A)(viii)), "such that the lone method covered in the '000 patent would not foreclose access to more affordable carvedilol." Teva's original "skinny label" listed its generic carvedilol as a treatment for *unpatented* treatments (e.g., hypertension), without mention of the patented heart failure treatment. The Chief Judge argued that the majority's opinion nullified Congress's statutory provision for "skinny labels," thereby slowing the introduction of lower-cost generics.

Regarding the later FDA-mandated full label (which listed treatment for heart failure as a use), the Chief Judge pointed to evidence that doctors did not actually read the label before prescribing, and that the switch from Coreg to the generic occurred automatically, often without the doctors' knowledge at all. Thus, there was no proof that the later full label specifically caused doctors to prescribe generic carvedilol in the infringing manner. Instead, the evidence showed that sources other than Teva induced doctors to prescribe the generic version.

In sum, the Chief Judge argued that the District Court Judge's job is to ensure that jury verdicts conform to the limits of the law and agreed with the District Court that the evidence of inducement was legally insufficient. In response, the majority simply dismissed the dissent, saying it applied the incorrect standard of review, and accused the Chief Judge of finding facts afresh rather than reviewing for substantial evidence.

The Heart of the Issue

This holding may have substantial impact on the marketing and labeling of generic drugs. In particular, even when a generic utilizes Congress's "skinny label" safe harbor in order to bring its generic version to market quicker for *unpatented* uses (while excluding patented uses from the label), inducement may still be found. A generic manufacturer's claim that the drug is therapeutically equivalent (e.g., "AB Rated") to the branded version could be used against the generic to show induced infringement of a patented course of treatment, even when the generic's materials excluded that patented use.