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Preview

The US Court of Appeals for the Federal Circuit reverses a judgment that upheld "skinny labels" and allowed a generic to launch on uses not covered by a patent *(GlaxoSmithKline / Teva)*

UNILATERAL PRACTICES, DOMINANCE (NOTION), DAMAGES, INTELLECTUAL PROPERTY, PHARMACEUTICAL, LICENSING, JUDICIAL REVIEW, NON-COMPETITION CLAUSE, UNITED STATES OF AMERICA, STANDARD ESSENTIAL PATENT

US Court of Appeals for the Federal Circuit, *GlaxoSmithKline / Teva*, Opinion, 2 October 2020

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e-Competitions News Issue Preview

On October 2, 2020, the U.S. Court of Appeals for the Federal Circuit vacated a district court's judgment in favor of defendant Teva in a case involving "skinny labels." *GlaxoSmithKline LLC v. Teva Pharm. USA, Inc.*, 976 F.3d 1347 (Fed. Cir. 2020). When a drug can be used to treat multiple conditions, a generic can "carve out" the patented indications from its label. 21 U.S.C. § 355(j)(2)(A)(viii) ("section viii"). The resulting "skinny label" allows the generic to launch its product for uses not covered by the patent.

GlaxoSmithKline LLC and SmithKline Beecham (Cork) Ltd. (together, "GSK") sued Teva Pharmaceuticals USA, Inc. (Teva) for patent infringement. After a trial in the U.S. District Court for the District of Delaware, the jury found the patent valid and infringed, and assessed damages. 976 F.3d at 1348. But the district court then granted Teva's motion for judgment of non-infringement as a matter of law.

The Federal Circuit, in a 2-1 decision written by Judge Newman, reinstated the jury verdict that Teva induced infringement of GlaxoSmithKline's patent. A vigorous, lengthy dissent from Chief Judge Prost disagreed with each of the majority's rulings.

Background

In 1985, GSK obtained a patent (the "'067 patent") covering a product called carvedilol, which the FDA approved to treat hypertension. *Id.* at 1349. After further study, scientists discovered that the drug also could treat congestive heart failure (CHF). In 1997, the FDA approved this treatment, and in 1998, GSK obtained the "'069 patent" for this use. *Id.*

In 2002, Teva sought FDA approval for a generic version of carvedilol. Teva certified that it would not launch its product until the '067 patent expired in 2007. GSK obtained a reissuance of the '069 patent – the "'000 patent" – in 2008, which covered the treatment of CHF. *Id.*

Between 2007 (when Teva introduced its product) and 2011 (when the FDA required Teva to amend its label to match GSK's label), Teva carved out the "indication and prescribing information for treatment of [CHF]." *Id.* at 1350. As a result, the FDA's final approval of Teva's generic application resulted in a "skinny label [that] was only indicated for hypertension and post-MI LVD [post-myocardial infarction with left ventricular dysfunction]"—neither of which was covered by any patent. *Id.* at 1361-62 (C.J. Prost, dissenting).

The jury nonetheless found that "Teva induced infringement of claims 1-3 during the period starting January 8, 2008 (the date of the '000 patent's issuance) to April 30, 2011 (the last day before Teva amended its label); and that Teva induced infringement of claims 1-3 and 6-9 during the amended label period starting May 1, 2011 and ending June 7, 2015 (the date of expiration of the '000 patent)." *Id.* at 1350-51. The jury assessed damages of $235 million and found that Teva's infringement was willful. *Id.* at 1351.

The district court granted Teva's motion for judgment as a matter of law, finding that substantial evidence did not support the induced-infringement verdict because "GSK failed to prove by a preponderance of the evidence that '*Teva's* alleged inducement, as opposed to other factors, actually *caused* the physicians . . . to directly infringe,' by prescribing generic carvedilol and to do so for the treatment of mild to severe CHF.'" *Id.* (emphasis in original).

The district court pointed to "many sources of information available to prescribing physicians, such as the American Heart Association, the American College of Cardiology, and various publications." *Id.* The court stated that "GSK's Coreg label and promotion of carvedilol had already informed physicians about the uses of Coreg" and that "[c]ardiologists testified that they knew of the various uses of carvedilol before the FDA required Teva to amend its label." *Id.* The court observed that "[a] reasonable factfinder could only have found that these alternative, non-Teva factors were what caused the doctors to prescribe generic carvedilol for an infringing use." *Id.* As a result, it concluded that "substantial evidence does not support the jury's finding on causation, and therefore does not support its verdict that Teva is liable for induced infringement, during both the skinny and full label periods." *Id.*

Majority Opinion

The Federal Circuit began its analysis by quoting Section 271(b) of the Patent Act, which provides that "[w]hoever actively induces infringement of a patent shall be liable as an infringer." *Id.* at 1352 (citing 35 U.S.C. § 271(b)). And it explained that "[a] plaintiff may . . . prove the intent element" of induced infringement "through circumstantial evidence." *Id.* at 1352.

Turning to the facts of the case, the Federal Circuit majority stated that "[t]he jury received evidence that Teva's promotional materials referred to Teva's carvedilol tablets as AB rated equivalents [therapeutic equivalents] of the Coreg tablets." *Id.* at 1353. There also was "evidence that Teva's 2007 press release remained on Teva's website" and that "Teva's Monthly Prescribing Reference, 2012 and 2013 editions, . . . state that they provide 'high-quality educational tools to serve as convenient, authoritative references in daily use.'" *Id.*

In addition to these materials, "[w]itnesses for both sides testified that cardiologists knew of carvedilol and the uses established for Coreg." *Id.* In particular, "GSK's witness . . . testified that doctors are 'completely reliant' on information provided by the generic producers, and that doctors receive Teva's product catalogs, visit its website, and read its product guides." *Id.*

Teva, in contrast, contended that "the 2004 and 2007 press releases should not be considered as evidence of inducement because the '000 patent was not issued until January 8, 2008." *Id.* at 1354-55. But the court found that "the evidence before the jury was that the 2007 press release remained on Teva's website throughout the life of the '000 patent." *Id.* at 1355.

The Federal Circuit found that the district court, in granting Teva's motion for non-infringement as a matter of law, "applied an incorrect legal standard," as "precedent makes clear that 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." *Id.* In particular, "[t]here was ample record evidence of promotional materials, press releases, product catalogs, the FDA labels, and testimony of witnesses from both sides, to support the jury verdict of inducement to infringe the designated claims for the period of the '000 reissue patent." *Id.*

The court stated that "[p]recedent has recognized that the content of the product label is evidence of inducement to infringe," with rulings "comport[ing] with precedent on causation in tort liability." *Id.* "Applying the standards of law and precedent," the court found "substantial evidence to support the jury's verdict of inducement to infringe the '000 patent." *Id.*

Finally, the court asserted that the issue was not "a policy debate about whether GSK made enough money from carvedilol in past years, and therefore should not be permitted to enforce its patent on its discovery of this novel method of prolonging life for persons with congestive heart failure," as this "is a policy matter for Congress." *Id.* at 1356. The court concluded that "there was substantial evidence to support the jury's findings of induced infringement throughout the term of the '000 patent." *Id.*

Dissent: Skinny Labels

Chief Judge Prost, in a critical dissent that was almost twice as long as the majority opinion, explained that "Congress designed the generic approval system with the express purpose of speeding the introduction of generic drugs to the market as soon as patents allow." *Id.* at 1357 (C.J. Prost, dissenting). Chief Judge Prost made clear that the panel's decision "undermines this balance 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." *Id.*

The dissent explained that Teva acted "as Congress intended," as it "waited until GSK's patent covering the carvedilol compound expired to launch its product covering two unpatented indications." *Id.* at 1358. Chief Judge Prost noted that "[a]ccording to the Majority, the 'content' of Teva's skinny label alone is sufficient to prove induced infringement—even though Teva's skinny label did not encourage, promote, recommend, *or even suggest* the patented method." *Id.* (emphasis in original). The dissent understood that the majority's holding "is no small matter," as "it nullifies Congress's statutory provision for skinny labels—creating liability for inducement where there should be none." *Id.* "Contrary to Congress's intent," Chief Judge Prost continued, "the Majority thereby allows one patented method to discourage generics from marketing skinny labels—thus, slowing, rather than speeding, the introduction of low-cost generics." *Id.*

The dissent also noted that "[i]n marketing its generic carvedilol, Teva *never* stated that it was approved, or could be used, to treat CHF." *Id.* at 1362 (emphasis in original). "In fact," the dissent continued, "the record suggests Teva hardly marketed its generic at all." *Id.* Moreover, GSK "failed to present evidence showing that doctors relied on the label in making prescribing decisions." *Id.* at 1364. "To the contrary," Chief Judge Prost observed, "GSK's expert . . . testified that *he had not read* the labels of other generic carvedilol products, and that he read Teva's label only 'in [the] context of [his] work on this case.'" *Id.* (emphasis in original).

The dissent explained that "[c]ontrary to the Majority's suggestion that Teva provided and marketed an 'identical product,' . . . Teva did not launch its product with a label that was identical to GSK's." *Id.* at 1366. In particular, "there is *no dispute* that the only two uses included on Teva's label, i.e., hypertension and post-MI LVD, *were not patented*." *Id.* (emphases in original). By "finding inducement based on Teva's skinny label, which was not indicated for—and did not otherwise describe—the patented method, the Majority invites a *claim of inducement* for almost *any generic* that legally enters the market *with a skinny label*." *Id.* (emphases in original).

Dissent: Facts

The dissent also criticized the majority's application of the law to the facts. It pointed out that the majority "exhumes Teva's press releases to establish infringement because they remained on Teva's website after the '000 patent's issuance." *Id.* at 1369. But Chief Judge Prost explained that "[t]he continued presence of the press releases . . . is not probative evidence of inducement," which requires "an affirmative act to encourage infringement" that was not satisfied by the "passive maintenance of the pre-issuance press releases." *Id.*

The dissent also found that "GSK did not produce any evidence during the skinny label period upon which a reasonable juror could conclude that Teva *encouraged* doctors to prescribe carvedilol to practice the patented method." *Id.* (emphasis in original). "Teva's press releases and product catalogs," the dissent found, did "not promote treating CHF at all." *Id.*

The dissent noted that "[w]ithout a disclosure of the claimed method, the Majority seems to rely on references to Teva's 'AB rating' or therapeutic equivalence as evidence of inducement," but it explained that these statements "cannot be legally sufficient to prove inducement" as "therapeutic equivalence is a designation provided by the FDA relating to the safety and efficacy of the drug compound" and "Orange Book determinations of therapeutic equivalence are not made for unapproved indications." *Id.* at 1370.

Chief Judge Prost also pointed out that "[t]hough circumstantial evidence may be sufficient evidence to prove inducement in some cases, this is not one of them." *Id.* at 1371. The reason is that "[b]eyond Teva's skinny label—which does not encourage doctors to practice the patented method—the only other evidence the Majority cites—i.e., press releases and product catalogs—are documents that do not describe the patented method, and for which little evidence, if any at all, even *hints* they were ever considered by doctors during the allegedly infringing period." *Id.* (emphasis in original). The dissent concluded that "[t]he inferences required to reach a finding of inducement exceed the bounds of reason." *Id.*

The dissent next explained that "uncontroverted record evidence establishes that it was other sources, and not Teva's label or other documents, that induced doctors to prescribe carvedilol according to the claimed method." *Id.* In particular, "the record confirmed that doctors prescribed carvedilol according to the claimed method based on the prescribing guidelines established by the American Heart Association and the American College of Cardiology, medical research studying carvedilol, and even GSK's own Coreg label and GSK's promotional materials advertising it." *Id.* at 1371-72. The dissent also noted that "the record showed that substitution of generic carvedilol for Coreg often happened without doctor involvement at all," as "automatic[] switch[ing] . . . did not even occur with the doctors' knowledge." *Id.* at 1372.

Author's reaction to opinion

In holding that the long-authorized and oft-trodden path to generic entry through skinny labels can lead to infringement, the majority opinion neglected several critical issues.

First, it failed to consider the regulatory framework. The pharmaceutical industry is unique in promoting not only innovation but also competition. The drafters of the Hatch Waxman Act sought to ensure the provision of "low-cost, generic drugs for millions of Americans," as generic competition would save consumers (and federal and state governments) millions of dollars each year and "do more to contain the cost of elderly care than perhaps anything else this Congress has passed." 130 Cong. Rec. 24427 (1984) (statement of Rep. Henry Waxman); *see also* Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37, 42 (2009). As the Supreme Court has recognized (and as Chief Judge Prost explained), the regime "is designed to speed the introduction of low-cost generic drugs to market." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012).

The majority opinion did not consider this legislative history or aspects of the regulatory regime that promote generic competition. Even though this is an essential element of the Hatch Waxman Act, the majority did not seem to recognize that its ruling could decimate the practice of skinny labeling. Chief Judge Prost understood that the majority's holding "is no small matter," as "it nullifies Congress's statutory provision for skinny labels" and "slow[s], rather than speed[s], the introduction of low-cost generics." 976 F.3d at 1357-58.

Second, related to the neglect of the legislative history and regulatory framework, the majority, as Chief Judge Prost pointed out, did not discuss Federal Circuit precedent holding that skinny labels do not induce infringement. For example, in *Warner-Lambert v. Apotex Corp.*, the Federal Circuit held that "the request to make and sell a drug labeled with a permissible (non-infringing) use cannot reasonably be interpreted as an act of infringement (induced or otherwise) with respect to a patent on an unapproved use," as the generic application "does not induce anyone to perform the unapproved acts required to infringe." 316 F.3d 1348, 1364-65 (Fed. Cir. 2003). And in *Takeda Pharmaceuticals U.S.A. v. West-Ward Pharmaceutical Corp.*, the Federal Circuit explained that "vague label language cannot be combined with speculation about how physicians may act to find inducement" and held that to induce infringement, a "label must encourage, recommend, or promote infringement." 785 F.3d 625, 631-32 (Fed. Cir. 2015). Nor is the omission of relevant precedent offset by cases addressing "causation in tort liability," 316 F.3d at 1355, that involved instruction manuals *encouraging* infringement, as opposed to skinny labels *lacking* instructions to infringe.

Third, the majority neglected to consider the unique advantages offered by section viii statements. For generics seeking to enter while a drug is covered by a patent, there are two options. A "Paragraph IV" certification allows a generic to certify that a patent "is invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). But this route has disadvantages. A Paragraph IV certification is treated as an act of infringement, which means that the brand company can sue and obtain lost-profit damages and an automatic 30-month stay of FDA approval. 35 U.S.C. § 271(e)(2)(A); 21 U.S.C. § 355(j)(5)(B)(iii). In contrast, the section viii route benefits generic firms. Because they need not provide notification to patent holders, they typically are not sued and are not subject to the 30-month stay. For generics seeking to enter the market quickly on only some of the drug's indications, section viii "speed[s] the introduction of low-cost generics." 976 F.3d at 1357; *see also Purepac Pharm. Co. v. Thompson*, 238 F. Supp. 2d 191, 195 (D.D.C. 2002), *aff'd*, 354 F.3d 877 (D.C. Cir. 2004) ("FDA may approve a section viii application immediately, making it an attractive route for generic manufacturers").

Fourth, the majority did not recognize the reliance interests upset by its decision. By holding generics liable for conduct that, until the ruling, was universally understood to be allowed—in fact, was a central element promoting generic competition—the majority sowed uncertainty. Chief Judge Prost pointed out that "Teva acted exactly as

Congress intended" but was found liable for $235 million in damages. 976 F.3d at 1358. Because generic firms that launch "at risk" could be required to pay a brand firm's lost profits (which far exceed what the generic typically makes since it sells its product at a fraction of the brand price), the potential liability could be staggering.

As Chief Judge Prost explained, the majority opinion raises multiple questions about whether causation can be shown based on Teva's press releases, product catalogs, and AB rating. But the potential decimation of a previously recognized valuable path for generics to enter the market is the most powerful consequence, threatening to undermine the careful balance at the heart of the pharmaceutical regime.