**2018-1976, -2023**

# United States Court of Appeals for the Federal Circuit

GLAXOSMITHKLINE LLC,
SMITHKLINE BEECHAM (CORK) LIMITED,

*Plaintiffs-Appellants*,

v.

TEVA PHARMACEUTICALS USA, INC.,

*Defendant-Cross-Appellant*.

Appeals from the United States District Court for the District of Delaware in Case No. 1:14-cv-00878-LPS-CJB, Chief Judge Leonard P. Stark.

**CORRECTED**

## BRIEF OF *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF GLAXOSMITHKLINE LLC AND SMITHKLINE BEECHAM (CORK) LIMITED

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July 27, 2018

# CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* Pharmaceutical Research and Manufacturers of America certifies the following:

1. The full name of every party or amicus represented by me is:

Pharmaceutical Research and Manufacturers of America

2. The name of the real party in interest represented by me is:

N/A

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

PhRMA has no parent corporation and no publicly traded company owns 10% or more of its stock. However, its membership includes companies that have issued stock or debt securities to the public. A list of PhRMA's members is available at: www.phrma.org/about/members.

4. The names of all law firms and the partners or associates that appeared for Pharmaceutical Research and Manufacturers of America in proceedings before the district court or are expected to appear in this Court are:

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA: David E. Korn

COVINGTON & BURLING LLP: Michael N. Kennedy, Steven Winkelman

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal are:

None.

Dated: July 27 2018 By: /s/ Michael N. Kennedy

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## INTEREST OF *AMICUS CURIAE*

The Pharmaceutical Research and Manufacturers of America ("PhRMA") represents leading biotechnology and pharmaceutical companies devoted to discovering and developing medicines.[1] Those efforts produce the cutting-edge treatments that save, prolong, and improve the quality of the lives of countless individuals every day. Since 2000, the Food and Drug Administration ("FDA") has approved more than 600 new medicines. For each new drug approval, however, many more drug candidates fail—often after expensive clinical trials—to generate sufficient evidence of safety and effectiveness to gain FDA approval. Given that significant failure rate, and FDA's stringent requirements to demonstrate safety and efficacy, new medicines are not obtained cheaply. In 2016 alone, PhRMA members invested an estimated $65.5 billion in researching and developing new medicines.

PhRMA members depend heavily on a robust system of patent rights and a fair system for adjudicating their validity. Accordingly, PhRMA seeks to advance public policies that foster innovation in pharmaceuticals, including by ensuring adequate patent protection to enable its members' substantial investments in research

[1] A complete list of PhRMA members is available at http://www.phrma.org/about/members. Members include Plaintiff-Appellant GlaxoSmithKline and Teva US Specialty Medicines, a corporate affiliate of Defendant-Cross-Appellant.

and development. One of the many ways in which PhRMA promotes pro-innovation public policy is by participating as *amicus curiae* before this Court.

All parties have consented to the filing of this brief.[2]

## ARGUMENT

In 1997, GSK launched Coreg®, the first beta-blocker for the treatment of congestive heart failure. Over the next decade, GSK educated doctors—with prescribing information, as well as promotional materials—in how to use Coreg® to treat congestive heart failure. The patent at issue in this case, U.S. Patent No. RE 40,000, covers one of Coreg®'s patented indications.

In 2007, Teva launched a generic version of Coreg® and, in 2011, Teva began marketing its generic for the treatment of congestive heart failure, the method of use claimed by GSK's patent. That same year, Teva began using a label identical to Coreg®'s labeling, after previously having "carved out" the patented congestive heart failure indication. GSK then sued Teva for patent infringement, alleging

[2] No party's counsel authored any portion of this brief. The above-listed attorneys from Covington & Burling LLP authored this brief, with input from PhRMA and its members. Covington attorneys have provided legal advice to Plaintiffs-Appellants GlaxoSmithKline and SmithKline Beecham (Cork) Limited ("Plaintiffs-Appellants"), but do not represent Plaintiffs-Appellants in this appeal and did not represent Plaintiffs-Appellants in the trial court. No party to this appeal or any person other than PhRMA, certain of its members not including GlaxoSmithKline LLC and Teva US Specialty Medicines, or its counsel contributed any money that was intended to fund preparing or submitting the brief.

among other things that Teva's marketing of its generic product induced infringement of the '000 patent.

At trial, GSK marshalled extensive evidence that Teva's marketing and other materials—including press releases, promotional materials, and catalogues distributed to doctor's offices—instructed doctors to use Teva's generic to treat heart failure in precisely the same manner as Coreg®. After considering this evidence, a jury found that Teva induced infringement and awarded to GSK more than $234 million in lost profits, with an additional $1.4 million in reasonable royalty damages.

GSK's vindication of its patent rights was short-lived. Disregarding the extensive evidence of Teva's inducement, the district court granted Teva judgment as a matter of law. Specifically, the district court held that no reasonable jury could find that "*Teva's* alleged inducement, as opposed to other factors, actually *caused* the physicians . . . to directly infringe." *GlaxoSmithKline LLC v. Teva Pharm. USA, Inc.*, No. 1:14-cv-878-LPS-CJB, 2018 WL 1517687, at *6 (D. Del. Mar. 28, 2018) (emphasis in original). The legal standard on which the district court's ruling was based rests on three fundamental misstatements and misapplications of law, all of which threaten to undermine the viability of enforcing method of treatment patents.

First, the district court effectively held that, to establish inducement, a patent holder must show that the alleged inducer's conduct was the *sole* cause of a third party's use of a product in an infringing manner. This has never been the law. Rather,

this Court has consistently held that an alleged inducer's actions need not be the exclusive, or even primary, cause of the inducement. Moreover, the standard articulated by the district court would allow inducers to avoid liability where an innovator brings a drug product to market and puts in the effort to educate doctors on how to use the product to treat patients. Since this will typically be the case prior to any generic launch, it is difficult to see how one could ever find a generic liable for infringement of a method patent under the district court's view of the law.

Second, the district court held that an innovator cannot rely exclusively on a generic's prescribing information to establish inducement when the generic has already begun marketing its product. That conclusion is once again contrary to precedent and further insulates inducers from liability and compounds the potential harm to innovators who expend resources to educate the market to use their patented products.

Third, the district court effectively adopted a *per se* rule that a generic label does not induce infringement where its indications do not expressly describe the patented method of treatment. That approach conflates the concepts of indications and patented methods, and is inconsistent with the rule set forth by this Court that a label should be assessed as a whole to determine whether it induces infringement.

It bears emphasis that the district court acknowledged the policy implications outlined above, which the parties raised in post-trial briefing. But instead of applying

a standard that would avoid those policy problems, the district court simply expressed its "hope[ ]" that "neither side is correct in its predictions as to the dire consequences of the Court's ruling." *GlaxoSmithKline*, 2018 WL 1517687, at *12 n.16. This Court should prevent, or at least ameliorate, any such adverse consequences by reaffirming the correct legal standard for determining induced infringement of a method of treatment patent.

For these reasons, *amicus curiae* urges the Court to reverse the district court's judgment.

## I. THE LEGAL STANDARD FOR INDUCEMENT APPLIED BY THE DISTRICT COURT RUNS CONTRARY TO ESTABLISHED PRECEDENT AND PUNISHES INNOVATORS BY SETTING AN UNDULY HIGH BAR FOR PROVING INFRINGEMENT.

In reaching its conclusion that Teva had not induced infringement of GSK's method patent, the district court applied the following legal standard: "To prove inducement, GSK was required to prove by a preponderance of the evidence that, among other things, 'Teva's alleged inducement, *as opposed to other factors*, actually *caused* the physicians to directly infringe.'" *GlaxoSmithKline*, 2018 WL 1517687, at *5. Under that standard, GSK had to prove that a physician's decision to prescribe Teva's generic version to treat chronic heart failure was caused by Teva's actions *alone*. This is not, and should not become, the law.

*First*, no decision from this Circuit holds that an accused inducer is liable only upon proof that it *exclusively* caused the underlying direct infringement. Instead, this

Court has explained that "[i]nducement requires such steps as encouraging, recommending, or promoting an infringing use." *ePlus, Inc. v. Lawson Software, Inc.*, 789 F.3d 1349, 1360 (Fed. Cir. 2015) (quotation marks, citations, and alterations omitted).[3] The Supreme Court has adopted a similar rule in copyright law. *See Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936-37 (2005) ("[O]ne who distributes a device with the object of promoting its use to infringe copyright, as shown by clear expression or other affirmative steps taken to foster infringement, is liable for the resulting acts of infringement by third parties.").

Precedent thus holds, contrary to the decision below, that an alleged inducer's conduct must be *a* contributing factor to direct infringement, not the *only* factor. "Indeed, [the Federal Circuit] ha[s] affirmed induced infringement verdicts based on circumstantial evidence of inducement (e.g., advertisements, user manuals) directed to a class of direct infringers (e.g., customers, end users) without requiring hard proof that any individual third-party direct infringer was actually persuaded to infringe by that material." *Power Integrations, Inc. v. Fairchild Semiconductor Int'l Inc.*, 843 F.3d 1315, 1335 (Fed. Cir. 2016); *see also id.* at 1331 (explaining inducement "requires successful communication between the alleged inducer and third-party

[3] The statute refers to "induce[ment]," which the Supreme Court has explained means "to lead on; to influence; to prevail on; to move by persuasion or influence." *Glob.-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 760 (2011) (alteration and quotation marks omitted). This definition of inducement hardly suggests that an inducer's actions must be the sole cause of infringement.

direct infringer"). By contrast, the district court's ruling would require a patentee to show that the alleged inducer's actions *exclusively* caused direct infringement.

*Second*, the standard applied by the district court penalizes an innovator for investing time and effort in teaching doctors to use a product for its intended use, insulates inducers from liability, and creates a significant free-rider problem. GSK instructed doctors to use Coreg® for the treatment of congestive heart failure for nearly ten years before Teva began marketing its generic version for the same use. Even if the district court were correct that "alternative, non-Teva factors were what caused the doctors to prescribe generic carvedilol for an infringing use," it is evident what those non-Teva factors were: GSK's efforts to instruct and educate doctors to use Coreg® to treat heart failure over the preceding decade. Indeed, even under the district court's characterization, there is little wonder that doctors could prescribe Teva's generic to treat heart failure without necessarily relying on Teva's label. GSK had already exerted tremendous effort to teach doctors how to use the product for that purpose, and Teva's generic copy free-rides on that effort. This problem looms particularly large where the inducer's marketing, like Teva's, leads doctors to believe that the generic is substitutable for the innovator's product.

In essence, the district court's ruling would allow inducers to avoid liability whenever, as here, the innovator has already educated the market on how to use a drug product before generic versions launch. The district court's rule punishes

innovators who bring new drugs to market and teach doctors and patients how to use them, while arguably incentivizing innovators not to educate doctors and patients about new uses of approved medicines. Moreover, by undermining the value of method of treatment patents, the standard imposed by the district court discourages companies from researching additional potential uses for already-approved drugs. Thus, the district court's standard is not only inconsistent with existing precedent, but is contrary to the public interest.

Compounding this error, the district court rejected the proposition that an innovator may rely on a generic's labeling to show inducement where "the innovator company published the results of clinical studies and promoted the patented use." *GlaxoSmithKline*, 2018 WL 1517687, at *11 n.14. Not only does that ruling undermine the public interest, as explained above, it runs contrary to a host of decisions that involved findings that a generic's labeling induced infringement of a method of treatment patent despite the fact that the innovator had presumably spent time marketing the reference product to doctors prior to the litigation. *See, e.g.*, *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1369 (Fed. Cir. 2017) (finding of induced infringement); *Warner Chilcott Co. v. Lupin Ltd.*, 580 F. App'x 911, 912 (Fed. Cir. 2014) (stipulation of induced infringement); *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042 (Fed. Cir. 2010) (finding of induced infringement);

*Sanofi v. Watson Labs. Inc.*, 875 F.3d 636, 646 (Fed. Cir. 2017) (finding of induced infringement).[4]

## II. THE DISTRICT COURT ERRED IN HOLDING THAT A PATENT OWNER MAY NOT RELY SOLELY ON A GENERIC'S LABEL TO PROVE INDUCEMENT.

The district court also determined that a patentee "cannot rely exclusively on the generic's label [to establish inducement] when the generic has already begun marketing its product." *GlaxoSmithKline*, 2018 WL 1517687, at *12 n.16. But this Court has held that a generic will be liable for inducement if it markets its products with a label instructing others to use the product in an infringing manner. As this Court has explained, "[u]nder § 271(e)(2)(A), a court must determine whether, if the drug were approved based upon the ANDA, the manufacture, use, or sale of that

[4] The district court attempted to distinguish *Sanofi* on the ground that it "involved the ordinary Hatch-Waxman framework, where a claim of induced infringement is filed before the generic has launched its product, and necessarily, *before* the generic has even attempted to communicate with any direct infringer." *GlaxoSmithKline*, 2018 WL 1517687, at *11 n.14 (quotation marks omitted). The court reasoned that where, as in this case, the generic has already launched, "inducement claims are not premised on a hypothetical, but instead must be supported by sufficient evidence as to what actually happened during the relevant time period." *Id.* The court's attempt to distinguish *Sanofi* is beside the point. Under the district court's incorrect legal standard, the dispositive issue is not whether the *generic* has communicated with any direct infringer, but whether the *innovator* has already communicated with physicians to teach them the method of use for which the generic seeks to market its product. Where the innovator has had such communications, the district court would allow generics to rely on the innovator's efforts, induce infringement, yet insulate themselves from liability.

drug would infringe the patent *in the conventional sense*." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997) (emphasis added).

This Court's decision in *AstraZeneca* is instructive. There, an innovator introduced a new product for the treatment of respiratory diseases. 633 F.3d at 1046. The innovator held method patents covering the approved indication. The alleged inducer sought to introduce a generic with a label "identical to the label included with" the patent holder's product. *Id.* at 1047. The innovator sought a preliminary injunction barring the alleged inducer from distributing the generic on, among other things, the ground that the proposed label would induce infringement. *Id.* Agreeing with the innovator "that the proposed label would cause *some* users to infringe the asserted method claims," *id.* at 1057 (emphasis added), the district court granted the preliminary injunction, *id.* at 1049. On appeal, this Court "affirm[ed] the district court's finding that AstraZeneca will likely prove induced infringement at trial." *Id.* at 1061.

Thus, the district court's conclusion that a patent holder may not exclusively rely on a generic's labeling to prove inducement runs directly contrary to this Court's precedent.

## III. THE DISTRICT COURT ERRED IN DETERMINING THAT TEVA'S "SKINNY" LABEL DID NOT INSTRUCT THE PATENTED METHOD.

The district court's ruling also implicates the provision of the Hatch-Waxman Act that permits generic ANDA filers to state that they are not seeking approval to sell their drug for a patented use, and requires them to prepare a label excluding indications that correspond to that patented use—so-called "section viii" carve-outs. *See* 21 U.S.C. § 355(j)(2)(A)(viii); 21 C.F.R. § 314.92(a).

Two weeks before launching its product, Teva stated in its ANDA for the first time that it would not sell its generic for use in GSK's patented method. Teva's original label purported to "carve out"—and thus not include—an indication for the treatment of mild-to-severe chronic heart failure. Teva used this version of the label, which the district court described as the "skinny label," from launch in 2007 until 2011. At that point, Teva began using a label identical to GSK's, which did include an indication for the treatment of congestive heart failure. The skinny label, however, contained sufficient information to induce doctors to prescribe the generic product in an infringing manner (*i.e.*, for the treatment of congestive heart failure). Specifically, the skinny label contained another indication for the treatment of "post-MI LVD"—a condition related to congestive heart failure—and thus encompassed instructions for treating heart failure. Based on evidence that the post-MI LVD

indication encouraged doctors to use the generic for the treatment of congestive heart failure, the jury found that Teva's skinny label induced infringement.

In concluding otherwise as a matter of law, the district court erroneously conflated the concepts of FDA-approved *indications*, on the one hand, and *patented uses*, on the other. The district court asserted that because Teva had carved out the "mild-to-severe congestive heart failure" indication from its skinny label, that label could not instruct the patented use. *GlaxoSmithKline*, 2018 WL 1517687, at *2-3, *7-8. The district court also rejected the jury's implicit finding, based on GSK's expert testimony, that the post-MI LVD indication in Teva's skinny label still instructed the claimed method. *Id.* at *7 n.9. In other words, the district court effectively adopted a *per se* rule that where a generic label does not include an indication *expressly* describing a patented use, with the same language used by the patent claims, the label cannot induce infringement as matter of law.

Although a drug indication and a patent claim drawn to a method of treatment are different things, the district court's rationale wrongly collapses them for purposes of assessing whether a carve-out label induces infringement. Adopting the district court's analysis will make it more difficult to enforce a method of treatment patent against an inducer when, for example, a patented method spans multiple drug indications, or even when the claim language does not match the indication language word-for-word. This Court should instead reaffirm the rule stated in *AstraZeneca*—

a skinny label should be assessed *as a whole* to determine if it would induce infringement by inevitably leading to the practice of the claimed method. 633 F.3d at 1060.

## CONCLUSION

For the foregoing reasons, *amicus curiae* urges the Court to reverse the district court's judgment of no inducement.

Dated: July 27, 2018

Respectfully submitted,

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## CERTIFICATE OF SERVICE

I, Michael N. Kennedy, hereby certify that, on July 27, 2018, the foregoing document was filed and served using the CM/ECF system.

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## CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rules of Appellate Procedure 29 and 32 and Federal Circuit Rule 32, I certify the following:

1. The brief complies with the type-volume limitations of Federal Rule of Appellate Procedure 29(a)(5) and 32(a)(7)(A) and Federal Circuit Rule 28.1. This brief contains 2,950 words, excluding the parts of the brief exempt by Federal Rule of Appellate Procedure 32(f).

2. The attached petition complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally space typeface using Microsoft Word 2016 in 14-point Times New Roman type style.

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